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Reregistration Eligibility Decision for Cypermethrin

List B

Case No. 2130

Reregistration Eligibility Decision (RED) Document
for
Cypermethrin

Approved by: _____
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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD ₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
μg/g	Micrograms Per Gram
μg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level

OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q ₁ *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Executive Summary

This document presents EPA's decision regarding the reregistration eligibility of the registered uses of cypermethrin. The Agency has conducted human health and ecological risk assessments based on reviews of the database supporting use patterns of the currently registered cypermethrin products. This document summarizes these risk assessments and describes the mitigation measures needed to address the identified risks.

Cypermethrin is an insecticide used both in agricultural and non-agricultural settings. Total cypermethrin use in the United States is approximately 1.0 million pounds of active ingredient (a.i.) per year. Approximately 140,000 pounds a.i. are used in agricultural crops, mainly on cotton (110,000 pounds), with minor uses on pecans, peanuts, broccoli and sweet corn. Treatment of cattle and other livestock accounts for approximately 1000 pounds a.i. per year. The great majority of cypermethrin use occurs in non-agricultural settings, including a wide range of commercial, industrial, and residential sites. Indoor pest control -mainly for control of ants, cockroaches, and fleas - accounts for about 110,000 pounds a.i., while outdoor structural, perimeter, and turf uses for control of subterranean termites and other insect pests accounts for nearly 750,000 pounds a.i. In residential settings, cypermethrin can be applied both by professional applicators and by residential users.

Cypermethrin was first registered in 1984 by FMC Corporation, who also subsequently registered the isomer enriched zeta-cypermethrin in 1992. Current technical registrants for cypermethrin included FMC, Syngenta, United Phosphorus International, and Valent BioSciences. Data for the two active ingredients is considered interchangeable. Since zeta-cypermethrin was registered after 1984, only cypermethrin is subject to reregistration. Cypermethrin is on reregistration List B; thus no Registration Standard was completed. Data call-ins (DCIs) for cypermethrin were issued in 1991 for basic toxicology and residue chemistry data, and in 1995 for handler exposure and worker re-entry data. Cypermethrin is one of nine synthetic pyrethroids registered on cotton, represented by the Pyrethroid Working Group (PWG), that are considered to be conditionally registered pending the development and review of data related to aquatic toxicity. EPA will make every effort to coordinate the implementation of its reregistration eligibility decision provisions and labeling for cypermethrin with the ongoing efforts of the PWG.

The Agency's human health effects and environmental fate risk assessment for cypermethrin included the assessment for zeta-cypermethrin as well, since zeta-cypermethrin is an S-enantiomer enriched formulation of cypermethrin, which is not distinguished from cypermethrin by the analytical enforcement method, and the toxicological endpoints are the same for both cypermethrin and zeta-cypermethrin.

Human Health Risk

Dietary Exposure (food only)

Refined acute (probabilistic) and chronic dietary exposure assessments were performed in order to determine the dietary (food only) exposure and risk estimates which result from the use of cypermethrin and zeta-cypermethrin in/on all registered crops. Actual residues from USDA PDP

monitoring data (collected during 1994, 1996, 1999, and 2001), estimated percent crop treated information, and processing factors, where available, were used. For acute exposure, the most highly exposed population subgroup was children 1-2 years old at 6.1% of the aPAD at the 99.9th percentile. For chronic exposure, the most highly exposed population subgroup was children 1-2 years old at 0.2% of the cPAD. Dietary exposures (both acute and chronic) estimates are below the Agency's level of concern for the general U.S. population and all population subgroups.

Drinking Water Exposure

The Estimated Drinking Water Concentrations (EDWCs) for cypermethrin were calculated using PRZM/EXAMS model (Tier II), based on the highest seasonal application rate (0.6 lb a.i./A on cotton). The estimated acute drinking water concentration in surface water is 1.04 ppb, and the estimated chronic drinking water concentration in surface water is 0.013 ppb. The SCI-GROW model was used to generate the EDWC for groundwater. The groundwater EDWC for both acute and chronic exposures is 0.0036 ppb.

Residential Exposure and Risk

Residential handler inhalation risks are below EPA's level of concern for all non-occupational handler scenarios. No short-term dermal exposures or risks were assessed for residential handlers since no dermal endpoints of concern were identified. EPA does not anticipate that residential handlers would have intermediate- or long-term exposures to cypermethrin or zeta-cypermethrin. Therefore, no intermediate- or long-term risks were assessed.

Residential /non-dietary post-application exposure to adults was assessed via the inhalation route, since no effects were observed in the dermal exposure study. Exposure to toddlers was assessed via the inhalation route, and via incidental oral exposure. All of these exposures are considered short term. Although cypermethrin can be used indoors as termiticide, long term exposure due to inhalation is considered negligible, since the vapor pressure for cypermethrin is extremely low. Inhalation risks to both adults and toddlers were below the Agency's level of concern. Individually, risks from hand to mouth exposure, object to mouth exposure, and incidental soil ingestion were all below EPA's level of concern.

Aggregate risk

An acute aggregate risk assessment was conducted taking into account risk from food and drinking water. EPA calculated the Drinking Water Levels of Comparison (DWLOC, which represents the maximum allowable exposure from drinking water that would still fall below EPA's level of concern) for all population subgroups. The acute DWLOC for the most highly exposed population subgroup (children 1-2 years old) is 940 ppb, which is much higher than the peak EDWC of 1.04 ppb in surface water and the maximum EDWC for ground water of 0.0036 ppb; therefore, acute aggregate risk estimates associated with exposure to cypermethrin residues in food and water do not exceed EPA's level of concern.

Short-term aggregate exposure takes into account residential exposure plus average exposure levels to food and water (considered to be a background exposure level). The calculated DWLOC value for children 1-2 years old is 890 ppb and this level is higher than the surface and ground water EDWCs of 0.013 and 0.0036 ppb.

Chronic aggregate assessment only includes food and water since chronic exposure from residential uses is negligible. The highest exposed population subgroup (children 1-2 years old) has a DWLOC value of 600 ppb, which is greater than the average annual EDWCs of 0.013 ppb for surface water and 0.0036 ppb for ground water. Therefore, chronic aggregate risk does not exceed the Agency's level of concern.

Cumulative

Cypermethrin is a member of the pyrethroid class of pesticides. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, available data shows that there are multiple types of sodium channels and that these compounds may act on different isoforms of the sodium channel and with other ion channels in producing their clinical signs. It is currently unknown whether the pyrethroids as a class have similar effects on all channels or whether modifications of different types of sodium channels would have a cumulative effect. Nor do we have a clear understanding of effects on key downstream neuronal function e.g., nerve excitability, or how these key events interact to produce their compound specific patterns of neurotoxicity. Without such understanding, there is no basis to make a common mechanism of toxicity finding. Therefore, EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids because the Agency has determined further study is needed regarding the assumptions of dose additivity and common mechanism(s) of toxicity to appropriately identify a group or subgroups for such an assessment. There is ongoing research by the EPA's Office of Research and Development and pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. The Agency anticipates the majority of this research to be completed by 2007.

FQPA Safety Factor

The Agency determined that the FQPA safety factor should be 1X since there are no residual uncertainties for pre and/or post natal toxicity, and the dietary (food and drinking water) and non-dietary exposure assessments will not underestimate the potential exposures for infants and children. No database uncertainty factor is needed since the toxicity database is complete.

Occupational Risk

Short-term, intermediate-term, and long-term risks to occupational handlers are below the Agency's level of concern with baseline attire (long sleeved shirt, long pants, shoes and socks), as long as wettable powder formulations are packaged in water soluble bags, and chemical resistant gloves are worn for hand-held application methods. Although risks could not be calculated for the one granular product of cypermethrin, risks would be lower than for liquid products which is below EPA's level of concern with baseline attire.

EPA did not assess occupational postapplication risks since no short- or intermediate-term dermal endpoints were identified and long-term dermal exposures are not expected for any of the registered use patterns. As per the Worker Protection Standard, a restricted-entry interval of 12 hours is required for agricultural uses.

Ecological Risk

The Agency's Tier I screening-level (deterministic) risk assessment is focused on maximum uses of cypermethrin on registered agricultural crops only, due to the difficulties of modeling and quantifying urban uses. As with several other pyrethroids, the great majority of cypermethrin use is non-agricultural. The non-agricultural applications of cypermethrin may result in exposure to aquatic organisms following runoff and/or erosion. The Agency recognizes the potential for aquatic toxicity from non-agricultural uses but was not able to quantify the risks due to lack of available data and acceptable models.

Aquatic Risk (fish, invertebrates)

For freshwater fish, invertebrates, and estuarine/marine fish, invertebrates, technical grade cypermethrin is very highly toxic on an acute basis. Cypermethrin formulations are also very highly toxic, with LC₅₀ values that are similar to those reported for technical grade cypermethrin. LOCs for acute risk (0.5) and acute endangered species risk (0.05) are exceeded for freshwater and estuarine/marine invertebrates for all six crop scenarios considered in this assessment. The highest acute RQs are observed for freshwater invertebrates, ranging from 49.4 to 558.3, exceeding all acute LOCs.

LOCs for chronic risk (1) are exceeded for freshwater and estuarine/marine invertebrates. The highest chronic RQs are observed for freshwater invertebrates, ranging from 57.6 to 325.4. All chronic RQs for freshwater fish and estuarine/marine fish are less than the chronic LOC (1).

Terrestrial Risk (birds, mammals)

For birds, all acute (dose-based and dietary-based) RQs are below the acute risk LOC (0.5) and the endangered species LOC (0.1) for all crop uses; chronic RQs are also below the LOC (1). The Agency's screening level ecological risk assessment for endangered species results in the determination that cypermethrin will have no direct acute or chronic effect on threatened and endangered birds.

For mammals, acute (dose-based) RQs are below the acute risk LOC (0.5). The acute endangered species LOC (0.1) is exceeded for 15g and 35g mammals feeding on short grass (dose-based RQs 0.1-0.2) for all crop scenarios. Mammalian chronic RQs (dose-based) range from <0.1 to 9.3 (15g mammals feeding on short grass in cotton), exceeding the chronic LOC (1) for most scenarios.

Plants

Toxicity data are not available for terrestrial plants; thus, risks associated with cypermethrin exposure to terrestrial plants cannot be assessed. However, based on the cypermethrin mode of action, phytotoxicity is not expected.

Non-target Insects

Cypermethrin exposure can present acute toxic risk to earthworms and to beneficial non-target insects, such as honey bees. This risk concern is extended to listed insects also.

Benefits and Alternatives

Usage data are sparse and generally do not distinguish between chemicals within the class. The recent loss of chlorpyrifos and diazinon for residential pest control has resulted in a greater reliance on pyrethrins and synthetic pyrethroids, as a class, among residential users. Most pyrethroids have similar efficacy and cost. In the absence of any one pyrethroid, homeowners and professional applicators would most likely simply substitute another pyrethroid insecticide. Users might also substitute insecticides from other chemical classes (e.g. organophosphates, carbamates, and neonicotinoids) and nonchemical control techniques (e.g. sanitation or exclusion). Given the options for substitution, economic impacts of restricting any one chemical would not likely be significant. The impact on risk of restricting any one chemical is uncertain and might increase given the substitutes available.

Risk Management

Human health risk

To address the handler risks of concern, the following mitigation is required:

(1) All wettable powder products must be packaged in water soluble bags including agricultural and residential (PCO/homeowner) products. Alternatively, replacing wettable powder products with products formulated as dry flowables would also reduce risks below the Agency's level of concern.

(2) Mixers/loaders/applicators using handheld equipment (all formulations) must wear chemical resistant gloves, in addition to baseline attire (long sleeved shirt, long pants, shoes and socks).

Ecological Risk

To address the ecological risks of concern, the following mitigation is required:

For agricultural uses:

- (1) Mitigation to address spray drift, including specifying minimum allowable droplet size and buffer zones, maximum allowable wind speed and release height on product labels.
- (2) Decreased application rates and increased application intervals.
- (3) A constructed and maintained vegetative buffer.

For non-agricultural uses (residential, commercial and industrial), mitigation includes limiting outdoor applications to impervious surfaces (such as sidewalks and driveways) to spot or crack and crevice treatments, and adding best management practices to product labels to reduce potential runoff to drains, sewers, or water bodies from outdoor nuisance pest and termite applications.

Reregistration Eligibility

The Agency has determined that cypermethrin is eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and labels are amended accordingly. In addition, where there are data gaps, data must be generated to confirm the reregistration eligibility decision documented in this RED. EPA will continue to work with cypermethrin and other pyrethroid registrants to better characterize aquatic risk from urban uses of the pyrethroids. More data are needed to characterize ecological risk, especially risk from urban uses. EPA will continue in registration review to ensure the periodic review of all pesticides to make sure they continue to meet current scientific and regulatory requirements, with the goal of reviewing each pesticide every fifteen years. The pyrethroids are tentatively scheduled for re-evaluation under the proposed Registration Review program in 2010.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as EPA review of all submitted data. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reassessment of all tolerances in effect on the day before it was enacted. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility among infants and children, and the cumulative effects of pesticides that have a common mechanism of toxicity. When the Agency determines that aggregate risks are not of concern and concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Cypermethrin is a member of the pyrethroid class of pesticides. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, available data shows that there are multiple types of sodium channels and that these compounds may act on different isoforms of the sodium channel and with other ion channels in producing their clinical signs. It is currently unknown whether the pyrethroids as a class have similar effects on all channels or whether modifications of different types of sodium channels would have a cumulative effect. Nor do we have a clear understanding of effects on key downstream neuronal function e.g., nerve excitability, or how these key events interact to produce their compound specific patterns of neurotoxicity. Without such understanding, there is no basis to make a common mechanism of toxicity finding. Therefore, EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids because the Agency has determined further study is needed regarding the assumptions of dose additivity and common mechanism(s) of toxicity to appropriately identify a group or subgroups for such an assessment. There is ongoing research by the EPA's Office of Research and Development and pyrethroid registrants to evaluate the differential biochemical

and physiological actions of pyrethroids in mammals. The Agency anticipates the majority of this research to be completed by 2007. When available, the Agency will consider this research and make a determination of common mechanism as a basis for assessing cumulative risk. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

The Agency made its reregistration eligibility determination based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered uses of cypermethrin are eligible for reregistration provided the mitigation and labeling outlined in the RED are implemented. The document consists of six sections: Section I, the introduction, contains the regulatory framework for reregistration/tolerance reassessment; Section II provides an overview of the chemical, including a profile of its use and usage; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency's reregistration eligibility, tolerance reassessment, and risk management decisions; Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV; and Section VI includes the appendices, related supporting documents and Data Call-In (DCI) information. The revised risk assessment documents and related addenda are not included in this document, but are available on the Agency's web page <http://www.epa.gov/pesticides>, and in the Public Docket at www.regulations.gov under docket number EPA-HQ-OPP-2005-0293.

II. Chemical Overview

A. Regulatory History

Cypermethrin was first conditionally registered in 1984 by FMC Corporation, who also subsequently registered an isomer enriched zeta-cypermethrin in 1992. Current technical registrants include FMC, Syngenta, United Phosphorus International, and Valent BioSciences. Data for the two active ingredients is considered interchangeable. Since zeta-cypermethrin was registered after 1984, only cypermethrin is subject to reregistration. Cypermethrin is on reregistration List B; thus no Registration Standard was completed. Data Call-ins (DCIs) for cypermethrin were issued in 1991 for basic toxicology and residue chemistry data, and in 1995 for handler exposure and worker re-entry data.

Cypermethrin is a synthetic pyrethroid insecticide. On June 14, 1984, the Agency conditionally registered a technical grade product and two end-use formulations each to ICI (now known as Syngenta Crop Protection) and FMC for use on cotton during the 1984 growing season. The original conditional registration for cypermethrin was subsequently renewed on January 9, 1985, and September 27, 1985. A conditional registration for cypermethrin use on pecans was issued on April 24, 1986. The conditional registration for use on lettuce (head) was issued on March 15, 1988.

Cypermethrin is one of nine synthetic pyrethroids registered on cotton, represented by the Pyrethroid Working Group (PWG), that are considered to be conditionally registered pending the development and review of data related to aquatic toxicity. EPA will make every effort to

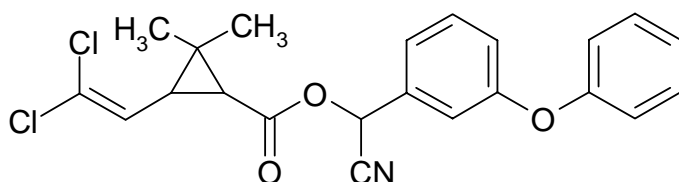
coordinate the implementation of its reregistration eligibility decision provisions and labeling for cypermethrin with the ongoing efforts of the PWG.

Due to the conditional status of the registration, tolerances were established for cypermethrin on a temporary basis on cottonseed, pecans, lettuce, meat, fat, and meat byproducts of hogs, horses, cattle, goats, sheep, and milk to cover residues expected to be present from use during the period of conditional registration. On July 31, 1996, tolerances were established for brassica (head and stem) and brassica (leafy). The conditional registrations for all cypermethrin uses were extended several times to November 15, 1993, November 15, 1994, November 15, 1995, November 15, 1996 and November 15, 1997. At the time of FQPA, cypermethrin's tolerances had expiration dates of 11/15/97. Agency policy was such that no temporary or time-limited tolerances were to be included among the official baseline number of tolerances which the Agency had to reassess. These tolerances were considered revoked with an expiration date and were expected not to need tolerance reassessment, nor need to be included in the tolerance reassessment baseline count.

On November 26, 1997, permanent tolerances were established for brassica (head and stem), brassica (leafy), cattle (fat), cattle (mbyp), cattle (meat), cottonseed, goats (fat), goats (mbyp), goats (meat), hogs (fat), hogs (mbyp), hogs (meat), horses (fat), horses (mbyp), horses (meat), lettuce (head), milk, onions (bulb), pecans, sheep (fat), sheep (mbyp), and sheep (meat). Such reassessments were not countable against the Agency's baseline number since they had not been included within the Agency's original tolerance reassessment baseline. Upon cypermethrin RED signature, no tolerance reassessments will be counted against the Agency's baseline number, nor were any previously counted.

B. Chemical Identification

Cypermethrin has the following structure:



Physical/Chemical Properties

Empirical Formula: $C_{22}H_{19}Cl_2NO_3$
Molecular Weight: 416.3
CAS Registry No.: 52315-07-8
PC Code: 109702
Melting Point: 60-80 degree C
Boiling Point: 216 degree C
Density: 1.204 g/mL at 25°C
Vapor Pressure: 3.1E-9 mm Hg at 20 degree C
Water Solubility: 7.6 ppb at 25 degree C
Log P (octanol-water): 6.60

Cypermethrin is a combination of 8 stereoisomers with percentage compositions ranging from 11-14%, and very low volatility and water solubility. Zeta-cypermethrin is an enriched enantiomer of cypermethrin consisting of the 4 stereo isomers with an “S” configuration at the cyano bearing carbon at 24% each, and 4 insecticidally less active stereo isomers at a concentration of 1% each. Since the analytical method does not distinguish cypermethrin from zeta-cypermethrin, and the toxicological endpoints are the same, the Agency’s human health risk assessment and environmental fate assessment considered both cypermethrin and zeta-cypermethrin.

C. Use Profiles

Type of Pesticide: Insecticide

Summary of Use: Cypermethrin is registered for agricultural use as a foliar application on food and feed crops including cotton, pecans, peanuts, broccoli and other Brassicas, and sweet corn. Cypermethrin can be applied to livestock in ear tags, and to horses. Cypermethrin is also registered for use on industrial, commercial, and residential sites. It is registered for outdoor use as a soil residual termiticide and to control insect pests such as ants in and on structures, impervious surfaces (in perimeter and crack and crevice treatments) and lawns. Cypermethrin can also be applied indoors to control ants, cockroaches, fleas, and other insects.

Target Organisms: Cypermethrin is registered for control of a wide range of pests.

Mode of Action: It is likely that the toxic action of pyrethroids is primarily due to their blocking action on some aspect of the synaptic function of the nerve axon.

Tolerances: There are 23 cypermethrin tolerances established under 40 CFR §180.418(a)(1) for pecans, bulb onions, cottonseed, head and stem brassica, green onions, head lettuce, leafy brassica and for the milk, fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep.

Use Classification: Agricultural products are restricted use. Residential, commercial, and industrial products are general use (can be purchased and applied by professional applicators or by residential applicators).

Formulation Types: Cypermethrin is formulated as an emulsifiable concentrate (EC), a soluble concentrate/liquid (SC/L), and a wettable powder (WP). Cypermethrin is compatible with a number of insecticides and fungicides, and has been formulated in products with two or more active ingredients.

Application Methods:	Applications to agricultural crops can be made with aircraft, chemigation, groundboom, and air blast equipment. Applications at industrial, commercial, and residential sites can be made using handheld equipment such as low-pressure handwand sprayers, backpack sprayers, hose-end sprayers, handgun sprayers, paintbrushes, and termiticide injectors, in addition to ready-to-use (RTU) aerosol cans, indoor foggers, pump-trigger sprayers, impregnated wipes and eartags.
Application Rates:	The currently labeled maximum application rates for agricultural uses range from 0.4 lbs. a.i./acre to 3.4 lbs. a.i./acre. The minimum retreatment intervals range from 3-7 days and the pre-harvest intervals (PHIs) range from 1 to 14 days. The maximum application rate for non-agricultural uses is 0.44 lbs ai/acre, for applications to lawns and turf.
Application Timing:	Cypermethrin agricultural products can be applied at various stages of crop development.
Usage of Cypermethrin:	<p>Total cypermethrin use is approximately 1.0 million pounds of active ingredient (a.i.) per year. In agriculture, it is used mainly on cotton (110,000 pounds a.i.) on about 13% of planted acres. Minor use is also found in several other crops including pecans (6,000 pounds a.i.), peanuts, broccoli and sweet corn (1 to 2 thousand pounds a.i each). Treatment of cattle and other livestock accounts for approximately 1,000 pounds a.i. per year.</p> <p>The great majority of cypermethrin use occurs in non-agricultural sites. Indoor pest control (mainly for ants, cockroaches, and fleas) accounts for about 110,000 pounds a.i., while outdoor use for subterranean termites and other insect pests accounts for nearly 750,000 pounds a.i. Of the non-agricultural use, approximately 300,000 pounds a.i. are applied by residential applicators, and 550,000 pounds a.i. by professional applicators.</p>

III. Summary of Cypermethrin Risk Assessments

The purpose of this section is to highlight the key features and findings of the risk assessments in order to help the reader better understand the risk management decisions reached by the Agency. While the risk assessments and related addenda are not included in this document, they are available in the OPP Public Docket <http://www.regulations.gov>.

A. Human Health Risk Assessment

The following is a summary of EPA's human health findings and conclusions for cypermethrin as presented fully in the document, "Cypermethrin: Phase 4 HED Risk Assessment for the Reregistration Eligibility Decision (RED). PC Code 109702; DP Barcode D293416. Dated 06-APR-2006.

1. Toxicity

Technical grade cypermethrin has moderate acute toxicity via the dermal and inhalation routes (Category III & IV), and is not a skin sensitizer. It is more toxic via the oral route (Category II).

Table 1: Acute Toxicity Profile				
Guideline No.	Study Type	MRID	Results	Toxicity Category
870.1000	Acute Oral - rat	00056800	LD ₅₀ (M): 247 mg/kg (F): 309 mg/kg females	II
870.1100	Acute Dermal	00056800	LD ₅₀ > 4920 mg/kg/day.	III
	Rat Rabbit	00056800	Abraded skin: LD ₅₀ > 2460 mg/kg.	
870.1200	Acute Inhalation - rat	42395702	LC ₅₀ : ♂ (not calculated but higher than ♀) LC ₅₀ : ♀ 2.5 (1.6-3.4) mg/L.	IV
870.2400	Primary Eye Irritation	00056800	Slight redness of conjunctivae, chemosis & discharge. Persisted to day 7.	III
870.2500	Primary Skin Irritation	00056800	Slight to mild erythema on intact & abraded skin. Reversed by 48 hours. Primary Irritation Index: 0.71	IV
870.2600	Dermal Sensitization	00056800 40377701	Not a sensitizer in Buehler assay. Moderate sensitizer in Magnusson Kligman Maximization method.	N/A

The toxicology database for cypermethrin is complete and there are no data gaps. The scientific quality is relatively high and the toxicity profile of cypermethrin can be characterized for all effects, including potential developmental, reproductive and neurotoxic effects. The data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.

Developmental and Reproductive Toxicity

Cypermethrin is not a developmental or reproductive toxicant. In prenatal developmental toxicity studies in rats and rabbits, there was no evidence of developmental toxicity at the highest

dose tested. In multi-generation reproduction studies in rats, offspring toxicity was observed at the same treatment level which resulted in parental systemic toxicity. There did not appear to be any increase in the severity of toxicity for the pups.

Neurotoxicity

Cypermethrin is a known neurotoxicant. It is a member of the pyrethroid class of insecticides, which are known to induce clinical signs of neurotoxicity in mammals, but do not generally induce neuropathologic lesions. For cypermethrin, neuromuscular effects (i.e. gait abnormalities, tremors, reduced motor activity, changes in FOB parameters and convulsions) occurred across species, sexes and routes of administration. These clinical signs occurred following an acute exposure and appeared to be transient in nature. Effects occurred mainly in oral studies in the dog and the rat, but similar signs were also observed in an inhalation study. Effects were not observed in dermal studies in either rats (zeta-cypermethrin) or rabbits (cypermethrin: nonabraded animals; abraded animals did exhibit decreases in activity).

Toxicological Endpoints

Table 2 contains endpoints selected for the dietary and residential assessments.

Table 2: Summary of Toxicological Doses and Endpoints for Use in Human Risk Assessments			
Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary general population including infants and children	NOAEL = 10 mg/kg/day UF = 100 Acute RfD = 0.1 mg/kg/day	FQPA SF = 1 aPAD = $\frac{\text{acute RfD}}{\text{FQPA SF}}$ = 0.1 mg/kg/day	MRID 44962201: Acute neurotoxicity study in the rat with zeta-cypermethrin. LOAEL = 50 mg/kg/day based on clinical signs of neurotoxicity and changes in the FOB.
Chronic Dietary <u>all populations</u>	NOAEL = 6 mg/kg/day UF = 100 Chronic RfD = 0.06 mg/kg/day	FQPA SF = 1 cPAD = $\frac{\text{chronic RfD}}{\text{FQPA SF}}$ = 0.06 mg/kg/day	MRID 44536801: Chronic feeding study in the dog. LOAEL = 20.4 mg/kg/day based on clinical signs of neurotoxicity and mortality in males, and 18.1 mg/kg/day based on decreased body weights and body weight gains in females.
Short-Term Incidental Oral (1 to 30 days)	NOAEL = 10 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = N/A	MRID 44962201: Acute neurotoxicity study in the rat with zeta-cypermethrin. LOAEL = 50 mg/kg/day based on clinical signs of neurotoxicity and changes in the FOB

Table 2: Summary of Toxicological Doses and Endpoints for Use in Human Risk Assessments			
Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Intermediate-Term Incidental Oral (1 - 6 months)	NOAEL= 5.0 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = N/A	MRID 44962202: Subchronic neurotoxicity study in the rat with zeta-cypermethrin. LOAEL = 26.3 mg/kg/day based on decreased motor activity, increased landing foot splay, and decreased body weights, body weight gains, and food consumption
Short- and Intermediate-Term Dermal (1 day to 6 months)	None	Residential LOC for MOE = N/A Occupational LOC for MOE = N/A	MRID 45010401: No systemic effects in 21-day dermal study with zeta-cypermethrin up to 1000 mg/kg/day and no developmental concern. No hazard identified to support quantification of risk.
Long-Term Dermal (> 6 months)	Oral NOAEL= 0.6 mg/kg/day (dermal absorption factor = 2.5%)	Occupational LOC for MOE = 100	MRID 44536801: Chronic feeding study in the dog. LOAEL = 20.4 mg/kg/day based on clinical signs of neurotoxicity and mortality in males, and 18.1 mg/kg/day based on decreased body weights and body weight gains in females.
Short- and Intermediate-Term Inhalation (1 day to 6 months)	Inhalation NOAEL= 0.01 mg a.i./L/day (2.7 mg/kg/day)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	MRID 43507101: 21-day inhalation study in the rat. LOAEL = 0.05 mg/L/day (13.5 mg/kg/day) based on decrease in body weight and salivation.
Long-Term Inhalation (> 6 months)	Inhalation NOAEL= 0.01 mg a.i./L (2.7 mg/kg/day)	Occupational LOC for MOE = 300 for the lack of long-term study. Route-to-route estimation would result in less protective endpoint.	MRID 43507101: 21-day inhalation study in the rat. LOAEL = 0.05 mg/L/day (13.5 mg/kg/day) based on decrease in body weight and salivation.
Cancer (oral, dermal, inhalation)	Classification: Category C (possible human carcinogen). No quantification required.		

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c= chronic), RfD = reference dose, MOE = margin of exposure, LOC = level of concern, N/A = not applicable.

2. FQPA Safety Factor

During the Agency's phase 3 reregistration process, an FQPA safety factor of 10x was retained due to database uncertainty (the lack of DNT study). The DNT study has now been submitted,

reviewed, and found to be acceptable. The Agency has determined that the FQPA safety factor should be reduced to 1X, since there are no residual uncertainties for pre- and/or post-natal toxicity. In addition, EPA has concluded that there is no need to change any previously-selected endpoints based on the submitted DNT, and that the dietary (food and drinking water) and non-dietary exposure assessments are protective of potential exposures to infants and children.

3. Dermal Absorption

A dermal absorption value of 2.5% has been estimated by comparing the maternal LOAEL of 25 mg/kg/day from the developmental study in the rat and the NOAEL (highest dose tested) of 1000 mg/kg/day from the 21-day dermal study in the rat (both conducted with zeta-cypermethrin). Since there was no common endpoint because no systemic effects were observed in the 21-day dermal study in the rat, this is considered to be a worst-case estimate.

4. Dietary Exposure

a. Acute Dietary Exposure (food only)

Zeta-cypermethrin is an S-enantiomer enriched formulation of cypermethrin. Since the analytical method does not distinguish cypermethrin from zeta-cypermethrin, and the toxicological endpoints are the same, the dietary and non-dietary (residential) aggregate risk assessment included potential exposures from both chemicals. The residue of concern for tolerance enforcement and risk assessment is the parent compound (cypermethrin) only. EPA performed a refined (probabilistic) acute dietary assessment using PDP data, percent crop treated information, and processing factors where appropriate. The assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 1.3), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998.

Dietary risk assessment incorporates both exposure to and toxicity of a given pesticide. Dietary risk is expressed as a percentage of a level of concern. The level of concern is the dose predicted to result in no unreasonable adverse health effects to any human population subgroup, including sensitive members of such population subgroups. This level of concern is referred to as the population adjusted dose (PAD), which reflects the reference dose (RfD), either acute or chronic, adjusted to account for the FQPA safety factor.

Estimated risks that are less than 100% of the PAD are below EPA's level of concern. The acute PAD (aPAD) is the highest predicted dose to which a person could be exposed on any given day with no adverse health effects expected. For cypermethrin, the acute risk estimates are below the Agency's level of concern (100% of the aPAD) for the general U.S. population and all population subgroups. The most highly exposed population subgroup was children 1-2 years old at 6.1% of the aPAD at the 99.9th percentile of exposure.

b. Chronic Dietary Exposure (food only)

A refined chronic dietary assessment was performed using PDP data, percent crop treated information, and processing factors where appropriate. The assessment was conducted using DEEM-FCID™, Version 1.3. The chronic PAD (cPAD) is the highest predicted dose to which a person could be exposed over the course of a lifetime with no adverse health effects expected. Chronic risk estimates for cypermethrin are below the Agency's level of concern (100% of the cPAD) for the general U.S. population and all population subgroups. The most highly exposed population subgroup was children 1-2 years old at 0.2% of the cPAD.

5. Drinking Water Exposure

(For a complete discussion, see the "Tier II Estimated Environmental Concentrations of Cypermethrin for the Use in the Human Health Risk Assessment" dated 05/02/2005, and the "Water Exposure/Risk, section 4.3 of the HED Chapter.)

Based on the available data, cypermethrin/zeta-cypermethrin is a moderately persistent chemical that primarily degrades by photolysis in water and biodegradation. Cypermethrin is hydrologically stable at neutral pH. Cypermethrin is more light stable than the first or second generation pyrethroids like allethrin and resmethrin, but still undergoes photolysis in water, with half-lives of about a month or more in distilled water. The rate of photolysis appears to be enhanced in natural waters (which contain photosensitizing agents like humic and fulvic acids), where it degrades with half-lives of a few days. It binds tightly to soil particles and is not likely to move to groundwater. The Agency has determined that the residue of toxicological concern to be included in drinking water assessment is the parent compound only.

The Estimated Drinking Water Concentrations (EDWCs) for cypermethrin were estimated using PRZM/EXAMS, based on modeling six aerial applications to cotton in North Carolina at the maximum application rate of 0.1 lbs a.i./A (for a yearly maximum of 0.6 lb a.i./A). According to the label, the maximum application rate is 0.6 lb a.i./A per season, so for certain crops like lettuce which have several growing seasons in one year, exposures could be higher. The exposure scenarios modeled assumed only one season per year. The estimated acute drinking water concentration in surface water is 1.04 ppb, and the estimated chronic drinking water concentration in surface water is 0.013 ppb (this value represents the mean over a 30-year period). Various other scenarios were also assessed (CA, MS and TX cotton, CA onion, and CA lettuce), but they consistently yielded lower EDWCs. The SCI-GROW model generated an EDWC for groundwater based on a maximum application rate for cypermethrin of six applications of 0.1 lbs a.i./A (this rate is representative of both cotton and lettuce). The groundwater EDWC for both acute and chronic exposures is 0.0036 ppb.

6. Residential Exposure and Risk

(For a complete discussion see, "Cypermethrin and Zeta-Cypermethrin: Revised Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document", dated April 5, 2006, DP barcode D293417).

The general public can be exposed to cypermethrin when applying the pesticide for indoor and outdoor residential pest control, or subsequent to applications made by residential applicators or professional applicators. Non-cancer risk estimates are expressed as a margin of exposure (MOE) which is a ratio of the dose from a toxicological study selected for risk assessment, typically a NOAEL, to the predicted exposure. Estimated MOEs are compared to a level of concern which reflects the dose selected for risk assessment and uncertainty factors (UFs) applied to that dose. The standard UF is 100x which includes 10x for interspecies extrapolation (to account for differences between laboratory animals and humans) and 10x for intraspecies variation (to account for differences between humans). Additional uncertainty or safety factors may also be applied. In the case of cypermethrin, EPA's level of concern is an MOE of 100.

a. Residential Handler Risk

No short-term dermal exposures or risks were assessed for cypermethrin, since no dermal endpoints of concern were identified. EPA does not anticipate that residential handlers would have intermediate- or long-term exposures to cypermethrin or zeta-cypermethrin. Therefore, no intermediate- or long-term risks were assessed.

EPA did assess short-term inhalation exposures and risks to residential handlers, for the following scenarios:

- Mixing/Loading/Applying Liquid concentrates with Low Pressure Handwand
- Mixing/Loading/Applying Liquid concentrates with Wipes
- Applying Ready to Use Formulations with a Pump Sprayer (PHED aerosol can data)
- Applying Ready to Use Formulations with Aerosol Cans
- Applying Ready to Use Formulations with Fogger
- Applying Ready to Use Formulations with Wipes

Residential inhalation risks are below EPA's level of concern (i.e., $MOE > 100$) for all non-occupational handler scenarios. All MOEs were greater than 16,000 which is below the Agency's level of concern.

A granular product was registered on February 23, 2006 (EPA registration # 28293-367). This product is for application to fire ant mounds on lawns and outside of homes. Similar products are registered for liquid zeta-cypermethrin and for liquid and wettable powder cypermethrin formulations. Due to lack of formulation-specific exposure data, no quantitative risk assessment could be conducted for the cypermethrin granular formulation. However, the Agency believes that the risk to residential handlers from exposure to this product will not exceed that for liquid products, which is below the EPA's level of concern.

b. Residential Post-application Risk

Since no effects were observed in any dermal exposure study, non-dietary post-application exposure to adults was assessed via the inhalation route only. Exposure to toddlers was assessed via the inhalation route, and via incidental oral exposure. All of these exposures are considered short term. Although cypermethrin can be used indoor as termiticide use, long term exposure

due to inhalation is considered negligible, since the vapor pressure for cypermethrin is extremely low. In general, post-application inhalation risks following outdoor applications are considered negligible as well.

Post-application inhalation risks following indoor fogger applications were assessed using time-weighted averages from a cyfluthrin room fogger air monitoring study. Post-application inhalation risks following indoor aerosol spray applications to carpets were assessed using air concentration estimates from the crack and crevice subset of PHED, and using a House Model to estimate an emission rate.

Inhalation risks to both adults and toddlers were below the Agency's level of concern (i.e., MOE > 100). All indoor inhalation MOEs for toddlers and adults were greater than 71,000 which is below the Agency's level of concern.

Post-application risks to toddlers from incidental oral ingestion were assessed using a short-term incidental oral endpoint (10 mg/kg/day). Incidental oral exposure to toddlers was assessed for the following scenarios:

- Hand to mouth activity on turf
- Object to mouth activity on turf
- Incidental soil ingestion
- Hand to mouth activity from indoor surfaces following crack & crevice treatments
- Hand to mouth activity from indoor surfaces following broadcast fogger treatments

The results indicate that risks from short-term incidental oral exposures were below EPA's level of concern for all indoor and outdoor scenarios, all MOEs were greater than 900.

7. Aggregate Exposure and Risk (food, drinking water, and residential)

In accordance with FQPA, the Agency must consider pesticide exposures and risks from all potential sources. These usually include food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, the Agency considers both the route and duration of exposure. Aggregate risk assessments for cypermethrin were conducted as follows: acute and chronic aggregate assessments were conducted based on food and water exposures, and short-term aggregate assessments were conducted based on food, water, and residential exposures. No intermediate- or long-term aggregate risk assessments were conducted because no intermediate- or long-term exposure scenarios are expected from residential uses of cypermethrin.

a. Acute Aggregate Risk (food and drinking water)

In order to calculate aggregate risk from exposure to cypermethrin residues in food and drinking water, EPA compared estimated cypermethrin concentrations in surface and groundwater (the EDWCs presented in section III.A.4.) with Drinking Water Levels of Comparison (DWLOCs). A

DWLOC is the portion of the PAD remaining after estimated dietary (food only) exposures have been subtracted, and the remaining exposure has been converted to a concentration in ppb. This concentration value, or DWLOC, represents the potential drinking water exposure that would still fall below EPA's level of concern. As long as the maximum EDWCs for surface and ground water are less than the DWLOC, aggregate risks from food and drinking water exposures are below EPA's level of concern.

In the case of cypermethrin, the lowest acute DWLOC of 940 ppb for children 1-2 years old is much higher than the peak EDWC of 1.04 ppb in surface water and 0.0036 ppb for ground water; therefore, acute aggregate risk estimates associated with exposure to cypermethrin residues in food and water do not exceed the Agency's level of concern.

b. Short-term Aggregate Risk (food, drinking water, and residential)

Short-term aggregate exposure takes into account residential exposure plus average exposure levels to food and water (considered to be a background exposure level). Cypermethrin residential uses constitute short-term exposure scenarios; endpoints have been selected for short-term incidental oral and inhalation exposures, and the acceptable MOE for all short-term exposures is 100. Since the toxicological effects through the inhalation exposure route are similar to the toxicological effects from oral exposures, the short-term aggregate risk assessment was conducted by adding the residential inhalation exposure, oral non-dietary exposure, and average food and water exposure. The incidental oral residential exposure value selected for the aggregate analysis was based on hand to mouth activity from indoor surfaces following crack and crevice treatment, as this scenario resulted in the highest calculated exposure level, and is therefore considered protective for all other exposure scenarios.

Short-term aggregate risk does not exceed Agency's level of concern for any population subgroup. The lowest DWLOC value of 890 ppb was calculated for children 1-2 years old and this level is higher than the surface and ground water EDWCs of 0.013 and 0.0036 ppb, respectively.

c. Chronic Aggregate Risk (food and drinking water)

Although cypermethrin can be used indoors as a termiticide, long term inhalation exposure is not expected due to its very low vapour pressure (3.1×10^{-9} mm Hg at 20 °C). Therefore, the chronic aggregate assessment only includes food and water. Chronic dietary estimates of exposure from food were taken from the dietary exposure model results described above. The calculated DWLOCs for children 1-2 years old has the lowest chronic DWLOC value of 600 ppb, which is greater than both the surface water (0.013 ppb) and ground water (0.0036 ppb) EDWCs; therefore, chronic aggregate risk estimates do not exceed the Agency's level of concern.

8. Occupational Exposure and Risk

For a complete discussion, see section 7.0 of the "Cypermethrin: Phase 4 HED Risk Assessment for the Reregistration Eligibility Decision (RED). PC Code 109702; DP Barcode D293416", dated April 6, 2006. Also, see "Cypermethrin and Zeta-Cypermethrin: Revised Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document",

dated April 5, 2006, DP barcode D293417. Although the occupational risk assessment included zeta-cypermethrin, only cypermethrin occupational assessment results are discussed here, since this reregistration decision applies only to cypermethrin products.

Workers can be exposed to cypermethrin through mixing, loading, and applying the pesticide for use on agricultural crops and livestock, and for use in indoor and outdoor industrial, commercial, and residential settings.

a. Occupational Handler Risk

Short- and intermediate-term dermal risks were not assessed for occupational handlers, since no short- or intermediate-term dermal endpoints were identified. Short and intermediate-term inhalation risks to handlers when mixing, loading, and applying cypermethrin products were assessed for the following agricultural and non-agricultural scenarios:

- Mixing and loading liquid and wettable powder formulations to support aerial, chemigation, groundboom, and airblast applications to agricultural crops
- Applying sprays with aerial, groundboom, or airblast equipment to agricultural crops
- Flagging to support aerial applications
- Mixing, loading, and applying liquid formulations using a low pressure handwand sprayer, a paint brush, a low pressure/high volume turf/handgun sprayer, or a termiticide injector
- Mixing, loading, and applying wettable powder formulations using a low pressure handwand sprayer, a paint brush, or a low pressure/high volume turf/handgun sprayer
- Mixing, loading, and applying wettable powder formulations packaged in water soluble bags using a low pressure/high volume turf/handgun sprayer
- Applying Ready-to-Use eartags, trigger pump sprayers, wipes, aerosol cans, or foggers

When data were available to assess risks, short- and intermediate-term inhalation risks to occupational handlers are below the Agency's level of concern (i.e., MOE >100) at baseline (long sleeved shirt, long pants, shoes and socks) for all formulations except the wettable powder. For handlers mixing and loading to support aerial applications to cotton (a high acreage crop), sodfarms, and agricultural uncultivated areas, fencerows and hedgerows, MOEs at baseline range from 4 to 37. The addition of engineering controls (packaging wettable powders in water soluble bags) reduces the risks to below EPA's level of concern for all scenarios. EPA has insufficient data to assess exposures to pilots in open cockpits. Inhalation risks to pilots in enclosed cockpits were below EPA's level of concern for all agricultural crop scenarios. No data are available to assess inhalation risks during the application of impregnated eartags; however, the risks are expected to be well below the inhalation risks (MOE=15,000) from applications using a ready-to-use aerosol can (considered to represent a worst case exposure scenario).

A few occupational handler exposure scenarios may be considered long-term, including applications to residential, commercial, and industrial turf by commercial lawn care operators and applications in and around residential, commercial, and industrial premises by commercial pest control operators. Since the toxicological endpoints of concern for long-term exposures are

based on similar adverse effects, long-term dermal and inhalation risks must be combined for occupational scenarios where long-term exposures are anticipated. The target MOEs for long-term occupational workers are 100 for dermal risk and 300 inhalation risk. Since these MOEs differ, an aggregate risk index (ARI) was used to assess combined long-term dermal and inhalation risks to handlers. The target ARI is 1; therefore, ARIs of less than 1 indicate potential risks of concern.

Long-term combined dermal and inhalation risks were assessed for the following scenarios:

- Mixing, loading, and applying liquid and wettable powder formulations using a low pressure handwand sprayer, a paint brush, or a low pressure/high volume turf/handgun sprayer
- Mixing, loading, and applying wettable powder formulations packaged in water soluble bags using a low pressure/high volume turf/handgun sprayer

Combined long-term dermal and inhalation risks are below EPA's level of concern for all scenarios involving liquid formulations at baseline attire or with the addition of chemical-resistant gloves to baseline attire. Combined long-term dermal and inhalation risks are below EPA's level of concern for all scenarios involving wettable powder formulations at baseline attire or with the addition of chemical-resistant gloves to baseline attire, except mixing/loading/applying wettable powders with a low-pressure handwand sprayer. Although data were not available to estimate the risks from mixing/loading and applying wettable powders packaged in water soluble bags with a low-pressure handwand sprayer, the risks are expected to be lower than for liquid products (below EPA's level of concern with the addition of chemical-resistant gloves to baseline attire). A similar reduction in risk would be expected if wettable powder products were reformulated into dry flowable formulations.

b. Occupational Post-application Risk

EPA did not assess occupational postapplication risks to agricultural workers following treatments to agricultural crops, since no short- or intermediate-term dermal endpoints of concern were identified and long-term dermal exposures are not expected for tasks involving any of the registered crop use patterns.

EPA did not assess occupational postapplication exposures and risks following applications of cypermethrin and zeta-cypermethrin to residential and commercial lawns, and in and around industrial, commercial, and residential premises, since no short- or intermediate-term dermal endpoints of concern were identified and long-term exposures are not expected for tasks involving any of the registered use patterns.

9. Human Incident Data

(For a complete discussion, see "Review of Cypermethrin Incident Reports. DP Barcode D293143, Chemical #109702", dated 08/26/2003.)

Pyrethroids, like cypermethrin, have relatively low toxicity to humans. Skin and eye irritation, nausea, vomiting, coughing and difficulty breathing were the most commonly reported symptoms. As with other pyrethroids, burning or tingling sensations are often reported by applicators (World Health Organization 1989). The occurrence of moderate and more serious symptoms was generally more prevalent among those exposed to cypermethrin than those exposed to other pesticides. Reports suggest that cypermethrin can cause asthma or asthma-like symptoms in susceptible individuals. See Section IV for further discussion of incidents and mitigation.

B. Environmental Risk Assessment

More detailed information can be found in the “Revised EFED Risk Assessment for the Reregistration Eligibility Decision (RED) on Cypermethrin After 30-Day “Error Only” Comment Period”, DP Barcode: D293412, dated October 25, 2005 and the “Addendum to the EFED RED Chapter for Cypermethrin”, DP Barcode D293413, dated June 9, 2006.

The majority of cypermethrin use occurs in non-agricultural sites. Non-agricultural applications of cypermethrin, such as perimeter treatments around buildings and applications to lawns, may result in exposure to aquatic organisms from surface runoff and/or erosion. Even though cypermethrin has a strong affinity to bind to soils and surfaces, residues at concentrations toxic to aquatic organisms have been measured in streams that receive runoff from suburban developments. A study recently conducted in an urban area of California found residues of cypermethrin and other pyrethroids in urban streams adjacent to residential areas and suggested that these areas are unlikely to be unique, particularly in dry regions where landscape irrigation can dominate seasonal flow in some water bodies. The Agency recognizes the potential for aquatic toxicity from non-agricultural uses. However, EPA was not able to assess the risks associated with urban runoff due to limited monitoring data and lack of acceptable models. The Agency’s future plans to assess non-agricultural uses of cypermethrin and other pyrethroids are discussed in Section IV.

The Agency’s Tier I screening-level (deterministic) risk assessment is focused on registered agricultural uses only. A summary of the Agency’s environmental fate assessment is presented below.

1. Environmental Fate and Transport

For the most part, the environmental fate data for cypermethrin were from studies on cypermethrin; however, some studies were conducted on zeta-cypermethrin as well as other isomers. Both cypermethrin and zeta-cypermethrin are expected to have similar fate in the environment.

Cypermethrin is expected to bind strongly to organic carbon and have little mobility in soil (K_{oc} values ranged from 20,800 to 385,000 L/kg), and therefore it is not likely to leach into groundwater. Due to its relatively low mobility, cypermethrin is most likely to reach adjacent bodies of water via spray drift, through runoff events accompanied by soil erosion, or in runoff from outdoor impervious surfaces. Cypermethrin is moderately persistent in the environment

and degrades through a combination of biotic and abiotic mechanisms. In soil, under both aerobic and anaerobic conditions, cypermethrin biodegrades relatively slowly, with half-lives on the order of about 2 months. In contrast, degradation is enhanced in water, with aerobic and anaerobic metabolism half-lives of 9 to 17 days. If released to surface water, cypermethrin partitions to sediment, where it may degrade more slowly. In terrestrial field dissipation studies, cypermethrin did not appear to persist in soil, where the major routes of degradation are photolysis and aerobic biodegradation. Degradation of cypermethrin through photolysis appears to be enhanced in natural waters which contain humic and fulvic acids. However, field studies conducted on rice (with zeta-cypermethrin) show high persistence in aquatic sediments. If cypermethrin is applied repeatedly, it is possible that the chemical can accumulate in the sediment in ever larger amounts, with slow biodegradation. Cypermethrin bioaccumulates moderately (488x) in fish.

2. Ecological Risk

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to non-target organisms from the use of cypermethrin products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose (LD₅₀) or the median lethal concentration (LC₅₀). These RQ values are then compared to the Agency's levels of concern (LOCs), which indicate whether a pesticide, when used as directed, has the potential to cause adverse effects to non-target organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern. These risks of concern may be addressed by further refinements of the risk assessment or mitigation measures. Use, toxicity, fate, and exposure are considered when characterizing the risk, as well as the levels of uncertainty in the assessment. EPA further characterizes ecological risk based on any reported incidents to non-target terrestrial or aquatic organisms in the field (e.g., fish or bird kills).

Table 3. EPA's Levels of Concern and Associated Risk Presumptions			
Risk Presumption	LOC Terrestrial Animals	LOC Aquatic Animals	LOC Plants
<i>Acute Risk</i> - there is potential for acute risk	0.5	0.5	1
<i>Acute Endangered Species</i> - endangered species may be adversely affected	0.1	0.05	1
<i>Chronic Risk</i> - there is potential for chronic risk	1	1	N/A

a. Risk to Aquatic Organisms

i. Fish and Invertebrate Toxicity

The results of acute toxicity studies in fish, invertebrates, and benthic organisms show that technical grade cypermethrin is very highly toxic on an acute basis. For freshwater fish and

estuarine/marine fish, the lowest toxicity values reported were an LC₅₀ of 0.39 µg a.i./L (rainbow trout), and an LC₅₀ of 0.95 µg a.i./L (sheepshead minnow), indicating that these organisms all have a similar susceptibility to cypermethrin. For freshwater invertebrates the lowest toxicity values reported were an LC₅₀ of 0.0036 µg a.i./L (waterflea) and for estuarine/marine invertebrates an LC₅₀ of 0.00475 µg ai/L (mysid shrimp), approximately 100 times lower than the toxicity values reported for fish. These results indicate that freshwater and estuarine/marine invertebrates are substantially more sensitive than other types of aquatic organisms to cypermethrin toxicity, and that they are expected to be at greatest risk for acute effects (death).

The available experimental LC₅₀ value for benthic amphipods is expressed in terms of sediment concentration of cypermethrin (LC₅₀ = 3.6 µg a.i./kg sediment). To assess risk to benthic organisms in terms of pore water, a surrogate benthic organism LC₅₀ value for pore water (0.00257 µg a.i./L pore water) was derived using the sediment LC₅₀ value and the average K_{oc} value (141,700) for cypermethrin. In oysters, cypermethrin is categorized as highly toxic (370 µg a.i./L).

Cypermethrin formulations are also very highly toxic, with LC₅₀ values that are similar to those reported for technical grade cypermethrin.

Table 4. Cypermethrin (Technical Grade) Acute Toxicity Reference Values for Aquatic Organisms.					
Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value (µg a.i./L)	Effects	Reference
Freshwater Fish	rainbow trout	96 hours	LC ₅₀ = 0.39 µg a.i./L	Morbidity	MRID 44546027
Freshwater Invertebrates	amiphod	48 hours	LC ₅₀ = 0.0036 µg a.i./L	Morbidity	MRID 44423501
Benthic Organisms	amphipod	10 days	<u>sediment value</u> (experimental data): LC ₅₀ = 3.6 µg a.i./kg sediment <u>pore water value</u> (derived data): LC ₅₀ = 0.00257 µg a.i./L pore water	Morbidity and Growth	MRID 44074406

Table 4. Cypermethrin (Technical Grade) Acute Toxicity Reference Values for Aquatic Organisms.

Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value ($\mu\text{g a.i./L}$)	Effects	Reference
Estuarine/ Marine Fish	sheepshead minnow	96 hours	$\text{LC}_{50} = 0.95 \mu\text{g a.i./L}$	Morbidity	MRID 90075
Estuarine/ Marine Invertebrates	mysid shrimp	96 hours	$\text{LC}_{50} = 0.00475 \mu\text{g a.i./L}$	Morbidity	Acc. No. 42444601

Chronic toxicity studies are available for freshwater fish and estuarine/marine invertebrates. Results in freshwater fish show that neonate survival is adversely affected by cypermethrin exposure ($\text{NOAEC} = 0.14 \mu\text{g a.i./L}$). For estuarine/marine invertebrates, chronic exposure to cypermethrin produced adverse effects on reproductive ($\text{NOAEC} = 0.0015 \mu\text{g a.i./L}$) and growth parameters ($\text{NOAEC} = 0.000781 \mu\text{g a.i./L}$).

Table 5. Cypermethrin (Technical Grade) Chronic Toxicity Reference Values for Aquatic Organisms.

Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value ($\mu\text{g a.i./L}$)	Effects	Reference
Freshwater Fish	fathead minnow	30 days	$\text{NOAEC} = 0.14 \mu\text{g a.i./L}$ $\text{LOAEC} = 0.33 \mu\text{g a.i./L}$	Growth and morbidity	MRID 89039
Freshwater Invertebrates	No adequate data submitted; to assess chronic risk to freshwater invertebrates, surrogate NOAEC value of $0.00059 \mu\text{g a.i./L}$ was derived based on the acute:chronic ratio method using acute and chronic data for estuarine/marine invertebrates.				
Benthic Organisms	No chronic data submitted; to assess chronic risk to benthic organisms, surrogate chronic NOAEC toxicity values for sediment of $0.59 \mu\text{g a.i./kg sediment}$ and for pore water of $0.00042 \mu\text{g a.i./L pore water}$ were derived based on the acute:chronic ratio method using acute and chronic data for estuarine/marine invertebrates.				
Estuarine/Marine Fish	No data submitted; to assess chronic risk to estuarine/marine fish, a surrogate NOAEC value of $0.34 \mu\text{g a.i./L}$ for sheepshead minnow was derived based on the acute:chronic ratio method using acute and chronic data for freshwater fish. e				

Table 5. Cypermethrin (Technical Grade) Chronic Toxicity Reference Values for Aquatic Organisms.

Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value (μg a.i./L)	Effects	Reference
Estuarine/ Marine Invertebrates	mysid shrimp	28 days	NOAEC = 0.000781 μg a.i./L LOAEC = 0.00197 μg ai/L	Weight of females reduced	MRID 42725301
			NOAEC = 0.0015 μg ai/L LOAEC = 0.0028 μg ai/L	Number of offspring reduced	

ii. Fish and Invertebrate Exposure

For exposure to aquatic fish and invertebrates, EPA considers surface water only, since most aquatic organisms are not found in ground water. Estimated environmental concentrations (EECs) for cypermethrin calculated using the Tier II PRZM/EXAMS models and employing maximum application rates, indicate that cypermethrin preferentially partitions to the sediment. Three crop usage scenarios, which constitute approximately 90% of cypermethrin's total crop usage, were considered: cotton, lettuce, and pecans. Modeling produced the highest EECs for cotton crops in North Carolina and Mississippi. A complete listing of EECs can be found in the EFED risk assessment, dated October 25, 2005.

iii. Fish and Invertebrate Risk

To assess risks of cypermethrin to non-target aquatic animals (*i.e.*, fish and invertebrates), EPA uses the peak concentration to derive RQs for acute exposure and the 21-day average concentration to derive RQs for chronic exposure. RQs are calculated as the concentration (peak or average EEC) divided by the relevant endpoint (LC_{50} for acute risk, NOAEC for chronic risk). Since results of acute toxicity studies in freshwater fish and invertebrates indicate that the major cypermethrin degradate (3-phenoxy benzoic acid) is much less toxic than the parent compound, EECs and RQs were derived only for the parent compound, not for total residue (parent plus degradates). Acute risk quotient (RQ) values were calculated using the endpoint from the most sensitive species tested within a taxonomic group.

Acute RQs for aquatic organisms are summarized in Table 6. The LOC for acute risk (LOC 0.5) is exceeded for all aquatic organisms and modeled crop scenarios, except CA cotton for freshwater invertebrates and estuarine/marine fish, and CA lettuce for estuarine/marine fish. LOCs for acute endangered species risk (LOC 0.05) are exceeded for freshwater fish and

invertebrates and estuarine/marine fish and invertebrates for all six crop scenarios assessed. The highest acute RQs are observed for freshwater invertebrates, ranging from 49.4 (CA cotton) to 558.3 (NC cotton), exceeding all acute LOCs.

Table 6. Acute RQs for Freshwater Fish, Freshwater Invertebrates, Estuarine/Marine Fish and Estuarine/Marine Invertebrates Exposed to Cypermethrin.					
Crop Use	PRZM/EXAMS Scenario	Freshwater Fish Acute RQ	Freshwater Invertebrate Acute RQ	Estuarine/Marine Fish Acute RQ	Estuarine/Marine Invertebrate Acute RQ
Cotton	California	0.5	49.4	0.2	37
	Mississippi	3.3	355.6	1.3	269
	North Carolina	5.2	558.3	2.1	423
	Texas	1.3	136.9	0.5	104
Pecans	Georgia	2.4	264.7	1.0	201
Lettuce (Head)	California	0.7	80.6	0.3	61

Chronic RQs for aquatic animals are summarized in Table 7. For freshwater invertebrates, chronic RQs range from 57.6 to 325.4 and for estuarine/marine invertebrates, chronic RQs range from 44 to 246 and, exceeding the chronic LOC (1). For freshwater fish and estuarine/marine fish, all chronic RQs are below the chronic LOC.

Table 7. Chronic RQs for Freshwater Fish, Freshwater Invertebrates, Estuarine/Marine Fish and Estuarine/Marine Invertebrates Exposed to Cypermethrin.					
Crop Use	PRZM/EXAMS Scenario	Freshwater Fish Chronic RQ	Freshwater Invertebrate Chronic RQ	Estuarine/Marine Fish Chronic RQ	Estuarine/Marine Invertebrate Chronic RQ
Cotton	California	0.2	93.2	0.1	70
	Mississippi	0.7	318.6	0.3	241
	North Carolina	0.7	325.4	0.3	246
	Texas	0.2	101.7	0.1	77
Pecans	Georgia	0.3	145.8	0.1	110
Lettuce (Head)	California	0.1	57.6	0.1	44

Sediment Exposure - Acute and Chronic Risk

Acute and chronic RQs have been derived for exposure of benthic organisms to sediments and pore water (Table 10). All acute and chronic RQs for benthic organisms exceed the LOCs for acute risk (LOC 0.5), acute endangered species risk (LOC 0.05) and chronic risk (LOC 1) for all modeled crop uses. There are several uncertainties regarding both acute and chronic RQs. Due to data gaps, acute RQs for pore water and chronic RQs for sediment and pore water were derived from estimated toxicity values based on the acute sediment toxicity value. However, there is considerable uncertainty surrounding the acute sediment toxicity value, since this value was obtained from a study using a water-sediment system that was not at equilibrium (sediment concentrations decreased throughout the exposure period).

Table 8. Acute and Chronic RQs for Benthic Organisms Exposed to Cypermethrin.					
Crop Use	PRZM/EXAMS Scenario	Sediment Acute RQ	Pore Water Acute RQ	Sediment Chronic RQ	Pore Water Chronic RQ
Cotton	California	7	2	35	9
	Mississippi	44	11	228	57
	North Carolina	48	12	244	60
	Texas	13	3	52	13
Pecans	Georgia	26	7	123	31
Lettuce (Head)	California	8	2	47	12

iv. Aquatic Plant Toxicity, Exposure and Risk

Toxicity data are not available for aquatic plants; thus, risks associated with cypermethrin exposure to aquatic plants could not be assessed. However, based on cypermethrin's mode of action, cypermethrin is not expected to be phytotoxic. In addition, the Agency is not aware of any plant incidents involving exposure to cypermethrin.

v. Effect of Buffers on Spray Drift

The screening-level risk assessment indicates that peak EECs exceed acute levels-of-concern for all aquatic taxa considered. The ecological risk assessment includes an evaluation of the relative contribution of runoff and spray drift to the exposure simulated by PRZM/EXAMS. A hypothetical scenario was run (for use on NC cotton) in which application of cypermethrin resulted in no spray drift. The resulting EEC of 2.2 µg a.i./L, which represented transport of cypermethrin to water via runoff and erosion alone, is high enough to exceed the acute LOC for all aquatic taxa.

The effect of a 150-foot spray buffer on potential exposure from runoff and erosion cannot currently be quantified. Presumably, the mass of cypermethrin that would be applied to that portion the field within 150 feet of a water body would be less than that applied to the rest of the crop, and would decline with distance. However, the PRZM model is an edge-of-field model which cannot simulate an untreated area between the field and the receiving water body.

The expected effect of a spray buffer on exposure through spray drift can be quantified using the AgDRIFT model, which was developed using extensive field data collected by the Spray Drift Task Force. This is important because while the EEC from PRZM/EXAMS used in the screening model represents a 1-in-10-year exposure from combined runoff/erosion and spray drift, the output from AgDRIFT can be made to represent the amount of exposure from spray drift that could occur any time a pesticide is applied.

AgDRIFT modeling for cypermethrin indicates that the exposure from spray drift alone could be sufficient to exceed levels of concern for aquatic organisms, and that implementation of a spray buffer can reduce that exposure significantly. Using typical spray conditions (10 ft. release height, 10 mph wind, and a fine-to-medium droplet size distribution [DSD]), the AgDRIFT model simulates a concentration of 0.73 µg a.i./L in the standard pond from spray drift if no buffer zone is observed. Risk quotients calculated with this EEC would exceed the acute LOCs of 0.5 for freshwater and estuarine/marine fish and invertebrates.

The table below shows the effect of spray buffers on the concentration of cypermethrin that AgDRIFT simulates in the standard pond. These values reflect the typical spray conditions described above, and an application rate of 0.1 lb ai/acre:

Table 9. Effect of Various Buffers on EECs					
Buffer (ft)	0	50	100	150	200
Concentration (µg a.i./L)	0.73	0.44	0.31	0.24	0.20

When a buffer of 150 feet is simulated, the resulting concentration of cypermethrin in the pond resulting from drift alone is reduced by two-thirds. This is sufficient to reduce the EEC below the acute level-of-concern of 0.5 for estuarine/marine fish ($RQ = 0.24 \mu\text{g a.i./L} / 0.95 \mu\text{g a.i./L} = 0.25$). This reduction would not reduce the risk quotients for drift alone below the acute LOC for freshwater fish (RQs of 0.61), but the reduction in exposure could lead to lower levels of mortality, and perhaps be sufficiently protective for less sensitive species. The toxicity reference values for freshwater and estuarine/marine invertebrates ($LC_{50} = 0.0036$ and $0.0048 \mu\text{g a.i./L}$, respectively) are so low that even a two-third reduction in exposure still results in RQs far above the LOC ($RQ = 67$ and 50 , respectively).

The use of a spray buffer would reduce exposure under conditions other than the typical conditions described above, but conditions more conducive to spray drift could result in unacceptable exposure from drift alone regardless of the buffer. For instance, if the wind speed (10 mph) and release height (10 ft) are kept the same as above, but a very fine-to-fine DSD is simulated instead of a fine-to-medium DSD, much greater exposure to cypermethrin could result.

Table 10. Effect of Various Buffers Using Fine-to-Fine Droplets on EECs					
Buffer (ft)	0	50	100	150	200
Concentration (µg a.i./L)	1.7	1.2	0.96	0.8	0.68

The resulting amount of spray drift would lead to more than three times the exposure at 150 feet than if the fine-to-medium DSD were used, and the resulting EECs would still exceed the LOC for all aquatic taxa.

In summary, a 150-foot no-spray buffer can result in significant reductions in exposure and risk to aquatic organisms, provided that application occurs under typical conditions and the DSD used for application is not too fine. Such exposure from spray drift alone can be expected any time cypermethrin is applied, regardless of whether a significant runoff/erosion event happens soon after.

vi. Risk to Aquatic Organisms from Non-Agricultural Uses

In addition to these potential acute and chronic risks from agricultural uses, aquatic organisms may be exposed to cypermethrin from non-agricultural uses, as well. The Agency has received and considered the results of a published study that measured pyrethroid residues in stream sediments adjacent to an urban subdivision in California. The study found toxic residue levels of

cypermethrin and other pyrethroids in stream sediments that receive runoff from the subdivisions via storm drains and summer over-irrigation of landscapes and lawns (Weston, *et al.*, 2005). Although bifenthrin was the major pyrethroid found, cypermethrin concentrations were also of toxic significance to aquatic invertebrates. Weston's work is significant because it documents the presence of pyrethroids in the sediments of creeks near residential areas. Since most of the use of cypermethrin is in non-agricultural settings, urban uses pose additional risks to aquatic systems that the Agency cannot quantitatively assess at this time. EPA currently is evaluating appropriate modeling approaches to assess risks from urban runoff (see Chapter IV for further discussion).

b. Risk to Terrestrial Organisms

i. Bird and Mammal Toxicity

Results of acute toxicity studies on birds suggest that cypermethrin is practically non-toxic to slightly toxic to avian species ($LD_{50} > 2,000$ mg a.i./kg body weight; $LC_{50} > 2,634$ mg a.i./kg diet) on an acute basis. Chronic avian studies showed no adverse effects at 50 mg a.i./kg diet (the highest dose tested), but the study was incomplete because a LOAEC was not determined

Mammalian data suggest that cypermethrin is moderately toxic ($LD_{50} = 247$ mg/kg body weight) on an acute basis. A chronic study in rats showed adverse effects (decreased body weight and body weight gain) in adults and offspring (NOAEC = 5.0 mg a.i./kg/ body weight/day; 100 mg a.i./kg diet).

Table 11. Cypermethrin Toxicity Reference Values for Terrestrial Organisms.				
Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value	Reference
Mammals				
Acute (Dose-based)	rat	single oral dose	LD_{50} (M): 247 mg/kg/ body wt	MRID 00056800
Chronic (Dietary-based and Dose-based)	rat	3 generation reproduction study	NOAEL (toxicity to parents and offspring) = 5.0 mg/kg/day LOAEC = (toxicity to parents and offspring) = 25 mg/kg/day	MRID 00090040
Birds				
Acute (Dose-based)	bobwhite quail	single oral dose	$LD_{50} > 2,000$ mg a.i./kg body wt	MRID 44546024
Acute (Dietary-based)	mallard duck	5-day dietary	$LC_{50} > 2,634$ mg a.i./kg diet	MRID 00090071

Table 11. Cypermethrin Toxicity Reference Values for Terrestrial Organisms.				
Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value	Reference
Chronic (Dietary-based)	mallard duck and bobwhite quail	Avian reproduction	NOAEC >50 mg a.i./kg diet	MRID 42322902
				MRID 42322901

ii. Bird and Mammal Exposure

The Agency assessed exposure to terrestrial organisms by first predicting the amount of cypermethrin residues found on animal food items and then using information on typical food consumption by various species of birds and mammals to determine the amount of pesticide consumed. The amount of residues on animal feed items is based on the Fletcher nomogram, which is a model developed by Hoerger and Kenaga (1972) and modified by Fletcher (1994), and the current maximum application rates for cypermethrin.

Estimated exposure concentrations for terrestrial receptors were determined using the standard screening-level exposure model, TREX (v.1.1), which is a simulation model that, in addition to incorporating the nomogram relationship, also includes pesticide degradation in the estimation of EECs. TREX considers exposure only in the area where cypermethrin is applied. The underlying assumption is that most, if not all, of the applied pesticide will settle in the use area. However, depending on weather conditions and type of application, spray drift of pesticides may occur, increasing the likelihood of wildlife exposure outside the use area. Since cypermethrin is applied via spray methods, spray drift is likely to occur and in some cases could be a significant source of exposure.

Four crop usage scenarios were assessed: cotton, pecans, lettuce, and canola. Cypermethrin maximum dose-based EECs ranged from 1.2-122 mg/kg body weight for birds, and 0.1-102 mg/kg body weight for mammals.

iii. Bird and Mammal Risk

For birds, all acute, dose-based and dietary based RQs are below the LOC for acute risk (LOC 0.5) and endangered species (LOC 0.1) for all crop uses. However, the acute endangered species LOC (0.1) is exceeded for 15g and 35g mammals feeding on short grass (dose-based RQs 0.1-0.2) for all crop scenarios, and for 15g mammals feeding on broadleaf plants/small insects in cotton (RQ = 0.11).

Chronic, dietary-based RQs for birds are all below the LOC for chronic risk (LOC 1). It was not possible to calculate a chronic dose-based RQ for birds because there were no acceptable dose-based toxicity values for birds available. For mammals, chronic, dose-based RQs range from <0.1 to 9.3 (15g mammals feeding on short grass in cotton), exceeding the chronic LOC (1) for

most scenarios. The chronic dietary-based RQ (1.1) exceeded the chronic LOC (1) for mammals feeding on short grass in cotton.

iv. Non-target Insect Toxicity, Exposure and Risk

Results of available toxicity studies indicate that cypermethrin is highly toxic to honey bees ($LD_{50} = 0.023 - 0.56 \text{ ug/bee}$) and very toxic to earthworms ($LC_{50} = 26.09 \text{ ug/cm}^2$) on an acute contact basis. Thus, honey bees and other non-target terrestrial invertebrates (*e.g.* beneficial insects and listed insects) are expected to be at risk for acute effects (lethality). No RQ values for non-target insects were derived; however, risks can be assessed qualitatively. Cypermethrin toxicity data show that it is very highly toxic to honey bees and is considered to be highly toxic on both a contact and an oral basis. Cypermethrin was also found to be highly toxic to honey bees exposed to foliage that had been sprayed with a cypermethrin formulation (Cymbush 3E). In addition, cypermethrin has also been shown to be highly toxic to earthworms. Based on these results, acute risks to non-target insects and terrestrial invertebrates are anticipated for the uses considered in this assessment.

v. Terrestrial Plants

As for aquatic plants, toxicity data are not available for terrestrial plants and risks could not be assessed. Cypermethrin is not expected to be phytotoxic based on its mode of action, and no incidents involving terrestrial plants have been reported to the Agency.

c. Ecological Incidents

A total of 10 aquatic incidents involving cypermethrin exposure have been reported to EPA and tracked by Ecological Incident Information System (EIIS). All incidents were categorized according to the Certainty Index as follows: possible (3 reports); probable (3 reports); and highly probable (4 reports). Although in about half of these aquatic incidents the source of cypermethrin was not reported, several fish kills were attributed to termiticide use of cypermethrin.

A total of five incidents involving terrestrial organisms (birds, goats, dog) were noted. The incident involving birds (5000 sparrows) was attributed to birds eating insects that had been killed from cypermethrin use the previous night on an eggplant crop.

d. Endangered Species Concerns

The Agency's screening level ecological risk assessment for endangered species results in the determination that cypermethrin will have no direct acute effects on threatened and endangered birds. However, potential indirect effects to any species dependent upon a species that experiences effects cannot be precluded from use of cypermethrin. These findings are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act.

For birds, all acute RQs are below the endangered species LOC (0.1) for all crop uses. The Agency's acute endangered species LOC for birds was not exceeded in the screening level assessment, but one incident involving acute effects on birds was reported.

For mammals, the acute endangered species LOC (0.1) is exceeded for 15g and 35g mammals feeding on short grass (dose-based RQs 0.1-0.2) for all crop scenarios and aquatic organisms (LOC = 0.05) were exceeded. The maximum calculated acute RQs for all organisms resulted from modeling cypermethrin use on North Carolina cotton; the maximum screening level acute RQs which exceed acute LOCs are shown in Table 12, below.

Table 12. Maximum acute RQs in screening level assessment.	
Organism	Maximum Acute RQ
Mammals	0.2
Freshwater fish	5.2
Freshwater invertebrates	558.3
Estuarine/marine fish	2.1
Estuarine/marine invertebrates	423
Benthic organisms (sediment exposure)	48
Benthic organisms (pore water exposure)	12

The Agency's screening level assessment results in the determination that cypermethrin will have no direct chronic effects on birds (all RQs are less than the chronic LOC of 1.0). However, the chronic LOC is exceeded for mammals, freshwater and estuarine/marine invertebrates, and benthic organisms. The maximum calculated chronic RQs for all organisms resulted from modeling cypermethrin use on North Carolina cotton; the maximum screening level chronic RQs which exceed the chronic LOC are shown in Table 13, below.

Table 13. Maximum chronic RQs in screening level assessment.	
Organism	Maximum Chronic RQ
Mammals (dose-based risk)	9.3
Freshwater invertebrates	325.4
Estuarine/marine invertebrates	246
Benthic organisms (sediment exposure)	244
Benthic organisms (pore water exposure)	60

No data were submitted to evaluate the risk of cypermethrin exposure to non-target terrestrial plants. However, the agency has determined that cypermethrin will have no effect on listed plants. Also, no incident reports have reliably linked cypermethrin or any other synthetic pyrethroid to phytotoxic effects despite the fact that pyrethroids are often applied on or near agricultural crops.

All of these findings are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act. Rather, this assessment serves as a screen to determine the need for any species specific assessments that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. That assessment refines the screening-level assessment to take into account the

geographic area of pesticide use in relation to the listed species, the habits and habitat requirements of the listed species, etc. If the Agency's species specific assessments result in the need to modify use of the pesticide in specific geographic areas, those changes to the pesticide's registration will take through the process described in the Agency's Federal Register Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility and Tolerance Reassessment

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic data to support reregistration of products containing cypermethrin and has determined that the data are sufficient to support reregistration.

The Agency has completed its assessment of the dietary, residential, occupational and ecological risk associated with the use of cypermethrin. Based on this assessment the Agency has sufficient information to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that cypermethrin containing products are eligible for reregistration provided that label amendments are made as outlined in this RED. Appendix A summarizes the uses of cypermethrin that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility, and lists the submitted studies that the Agency found acceptable.

Based on its evaluation of cypermethrin, the Agency has determined that cypermethrin products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA and FQPA. Accordingly, should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address the risk concerns from the use of cypermethrin. If all changes outlined in this document are incorporated into the product labels, then all current risks for cypermethrin will be adequately mitigated for the purposes of this determination. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained under "Endangered Species Concerns" above.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for cypermethrin. EPA released its cypermethrin preliminary risk assessments for public comment on December 28, 2005, for a 60-day public comment period (Phase 3 of the public participation process). During the public comment period, the Agency received comments from the technical registrants, the California water quality control boards, the California Stormwater Quality Association, and other stakeholders. These comments in their entirety, responses to the comments, as well as the preliminary and

revised risk assessments, are available in the public docket (EPA-HQ-OPP-2005-0293) at <http://www.regulations.gov>.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. “Risk Cup” Determination

Even though cypermethrin tolerances are not included in EPA’s baseline tolerance reassessment counts, EPA assessed the risks associated with cypermethrin. EPA has concluded that the tolerances for cypermethrin meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food and residential sources.

b. Determination of Safety to U.S. Population

The Agency has determined that the established tolerances for cypermethrin, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, as amended by FQPA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of cypermethrin. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices, and the environmental behavior of cypermethrin. As discussed in Section III, aggregate acute, short-, intermediate-, and long-term risks from food, drinking water, and residential exposures are below the Agency’s LOC.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerances for cypermethrin, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors on the toxicity, use practices and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of cypermethrin residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of cypermethrin, the Agency considered the completeness of the hazard database for developmental and reproductive effects including a developmental neurotox study, the nature of the effects observed, and other information. The FQPA Safety Factor has been reduced to 1X, because there are no residual uncertainties for pre- and/or post-natal toxicity, exposure is not underestimated, and there is no evidence of increased susceptibility.

2. Endocrine Disruptor Effects

The available database provides no evidence that cypermethrin induces endocrine disruption.

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate.” Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). In the available toxicity studies on cypermethrin submitted for registration purposes, there was no estrogen, androgen, and/or thyroid mediated toxicity. When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, cypermethrin may be subject to additional screening and/or testing.

3. Cumulative Risks

Cypermethrin is a member of the pyrethroid class of pesticides. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, available data shows that there are multiple types of sodium channels and that these compounds may act on different isoforms of the sodium channel and with other ion channels in producing their clinical signs. It is currently unknown whether the pyrethroids as a class have similar effects on all channels or whether modifications of different types of sodium channels would have a cumulative effect. Nor do we have a clear understanding of effects on key downstream neuronal function e.g., nerve excitability, or how these key events interact to produce their compound specific patterns of neurotoxicity. Without such understanding, there is no basis to make a common mechanism of toxicity finding. Therefore, EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids because the Agency has determined further study is needed regarding the assumptions of dose additivity and common mechanism(s) of toxicity to appropriately identify a group or subgroups for such an assessment. There is ongoing research by the EPA’s Office of Research and Development and pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. The Agency anticipates the majority of this research to be completed by 2007. When available, the Agency will consider this research and make a determination of common mechanism as a basis for assessing cumulative risk. For information regarding EPA’s procedures for cumulating effects from substances found to have a common mechanism on EPA’s website at <http://www.epa.gov/pesticides/cumulative/>.

D. Tolerance Reassessment Summary

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for cypermethrin residues in/on various plant and livestock commodities. The Codex and U.S. tolerances are in harmony with respect to MRL/tolerance expression. Both regulate the parent compound, cypermethrin.

Special efforts to increase harmony between recommended US tolerance levels and Codex MRLs were made for the following commodities: 1) poultry, meat (0.05 ppm instead of no tolerance), and 2) meat of cattle, goat, sheep, and horse (0.20 instead of 0.05 ppm). The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs with respect to MRL/tolerance level: (i) compatibility between the U.S. tolerances and Codex MRLs exists for bulb onions; meat byproducts; poultry, meat; and meat of cattle, goat, sheep, and horse; and (ii) incompatibility of the U.S. tolerances and Codex MRLs remains for Brassica vegetables, cottonseed, lettuce, and milk, because of differences in good agricultural practices and determination of secondary residue levels in livestock commodities. No questions of compatibility exist with respect to commodities where Codex MRLs have been established but U.S. tolerances do not exist, or vice versa.

A summary of cypermethrin tolerance reassessments is presented in Table 14.

Table 14. Tolerance Reassessment Summary for Cypermethrin.			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Tolerances listed under 40 CFR 180.418(a)(1):			
Brassica, head and stem	2.0	2.0	[<i>Brassica, head and stem, subgroup</i>]
Brassica, leafy	14.0	14.0	[<i>Brassica, leafy greens, subgroup</i>]
Cattle, fat	0.05	1.0	
Cattle, meat	0.05	0.20	Harmonize with Codex MRL
Cattle, mbyp	0.05	0.05	[<i>Cattle, meat byproducts</i>]
Cottonseed	0.5	0.50	[<i>Cotton, undelinted seed</i>]
Goats, fat	0.05	1.0	[<i>Goat, fat</i>]
Goats, meat	0.05	0.20	[<i>Goat, meat</i>] Harmonize with Codex MRL
Goats, mbyp	0.05	0.05	[<i>Goat, meat byproducts</i>]
Hogs, fat	0.05	0.10	[<i>Hog, fat</i>]
Hogs, meat	0.05	0.05	[<i>Hog, meat</i>]
Hogs, mbyp	0.05	—	Residue data support removal of tolerance.
Horses, fat	0.05	1.0	[<i>Horse, fat</i>]

Table 14. Tolerance Reassessment Summary for Cypermethrin.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Horses, meat	0.05	0.20	[Horse, meat] Harmonize with Codex MRL
Horses, mbyyp	0.05	0.05	[Horse, meat byproducts]
Lettuce, head	10.0	4.0	Residue data support reduction of tolerance.
Milk	0.05	2.5	[Milk, fat (reflecting 0.10 in whole milk)]
Onions, bulb	0.1	0.10	[Onion, bulb]
Onions, green	6.0	6.0	Residue data support a tolerance level of 3.0 ppm for zeta-cypermethrin / [Onion, green]
Pecans	0.05	0.05	
Sheep, fat	0.05	1.0	
Sheep, meat	0.05	0.20	Harmonizes with Codex MRL
Sheep, mbyyp	0.05	0.05	[Sheep, meat byproducts]
Tolerances That Need To Be Proposed under 40 CFR 180.418(a)(1):			
Cotton gin byproducts	--	11	
Egg	–	0.05	
Poultry, fat	–	0.05	
Poultry, meat	–	0.05	Harmonizes with Codex MRL
Tolerances That Need To Be Changed under 40 CFR 180.418(a)(2):			
Hog, fat	1.0	0.10	Updated dietary burden supports lower tolerance level.
Hog, meat	0.2	0.05	Updated dietary burden supports lower tolerance level.
Hog, meat byproducts	0.05	None	Updated dietary burden eliminates need for tolerance.
Lettuce, head	10.00	None	Covered by Vegetable, leafy, except Brassica, group 04.
Poultry, meat byproducts	0.05	None	Updated dietary burden eliminates need for tolerance.

E. Regulatory Rationale

The Agency has determined that cypermethrin is eligible for reregistration provided that the risk mitigation measures and label amendments specified in this RED are implemented. The

following is a summary of the rationale for managing risks associated with the use of cypermethrin.

1. Human Health Risk Mitigation

a. Dietary, drinking water, residential, and aggregate risk mitigation

Cypermethrin dietary (food + drinking water), residential, and aggregate risks were below the Agency's level of concern. Moreover, the risk assessments are protective of the general U.S. population and all population subgroups, including infants and young children. Therefore, no mitigation is necessary for these scenarios.

b. Worker risk mitigation

i. Handler risk mitigation

A number of application scenarios involving aerial, ground, or handheld equipment result in risks above EPA's level of concern ($MOE < 100$ or $ARI < 1$). The following mitigation measures are necessary to address occupational risks that exceed the Agency's level of concern:

Mixing, loading and applying liquid formulations

For motorized ground and aerial equipment, risks are below EPA's level of concern at baseline and therefore, no mitigation is needed. For handheld application equipment, risks are below the level of concern with the addition of chemical resistant gloves.

- For liquid formulations, chemical-resistant gloves are required for all hand-held application methods.

Mixing, loading and applying wettable powder formulations

- For wettable powder formulations, all products must be repackaged in water soluble bags.
- For wettable powder formulations, chemical-resistant gloves are required for all hand-held application methods.

One registrant with a wettable powder product for use in industrial, commercial, and residential settings has requested to reformulate their product into a dry flowable or prill formulation, rather than repackaging it into water soluble bags. Although risks can not be calculated due to lack of exposure data for dry flowables, EPA is confident that the risks to mixer, loader, and applicators of dry flowables products would be lower than those for liquid products, and thus below the Agency's level of concern with the addition of chemical resistant gloves.

- For dry-flowable or prill formulations, chemical-resistant gloves are required for all hand-held application methods.

Additional mitigation for aerial applications

- Closed cockpits are required.
- Human flagging is prohibited.

The human health assessment estimated risks to mixers, loaders and applicators making groundboom and aerial applications to sod farms at 0.74 lbs a.i./A. Application to sod farms is allowed through two Special Local Need registrations (FL SLN 890033, and CA SLN 840214). The Florida SLN allows application to Anheuser Busch sod farms using a soil injection rig only. The registrant (Syngenta) has been unable to verify whether or not this SLN is still in use and is not opposed to canceling it, since it is still tied to a former registrant's product and has never been updated to reflect the change of product ownership. In any case, EPA does not anticipate risks of concern to human health (or aquatic organisms) from this soil injection use on sod farms. The California SLN allows both groundboom and aerial application to sod farms. The registrant (FMC) has no record of this SLN and does not think it is currently active.

- Withdraw FL SLN 890033 and CA SLN 840214, for use on sod farms

Mixing, loading and applying granular formulations

In February 2006, a granular product was registered for use on lawns and outside of homes to kill fire ants (application to fire ant mounds). Although no data were available to assess the risks of this use for cypermethrin, the Agency believes that the risks from this granular cypermethrin product will not exceed those for liquid products, which are below EPA's level of concern for this scenario. No mitigation is needed for this use.

Applying ready-to-use (RTU) formulations

No risks exceeded EPA's level of concern, and no mitigation is needed.

ii. Post-application risk mitigation

Agricultural uses

EPA did not assess occupational postapplication risks to agricultural workers following treatments to agricultural crops, since no short- or intermediate-term dermal endpoints of concern were identified and long-term dermal exposures are not expected for tasks involving any of the registered crop use patterns.

- As per the Worker Protection Standard, a restricted-entry interval of 12 hours is required for agricultural uses.

Non-agricultural (industrial, commercial, and residential) uses

EPA did not assess occupational post-application exposures and risks following applications to residential and commercial lawns, and in and around industrial, commercial, and residential premises, since no short- or intermediate-term dermal endpoints of concern were identified and long-term exposures are not expected for tasks involving any of the registered use patterns.

- No new mitigation is required, but existing precautionary label statements and use directions intended to be protective of human health must be retained (see label table in Section V. for examples).

iii. Additional recommendations based on incident reports

Based on documented incident reports involving cypermethrin, skin and eye protection is recommended for agricultural handlers making broadcast applications. Bystanders should vacate indoor areas receiving treatment and the area should be appropriately ventilated afterwards before persons reenter the premises. Further study is needed to determine whether labels should advise of potential allergy or asthma-like problems among sensitive individuals.

2. Environmental Risk Mitigation

The Agency has conducted a screening-level ecological and environmental risk assessment for the registered agricultural uses of cypermethrin. Based on the available data, the Agency has identified potential acute risks of concern to freshwater and estuarine/marine invertebrates and fish, benthic organisms, mammals, earthworms, and non-target insects, and potential chronic risks of concern to freshwater and estuarine/marine invertebrates, benthic organisms, and mammals.

Risk from non-agricultural uses of cypermethrin could not be quantitatively assessed at this time, but is expected based on the risks from agricultural uses, the high proportion of use of cypermethrin in outdoor non-agricultural areas (e.g. for nuisance pest control around structures and on lawns, and as a pre-construction termiticide), and the limited existing data showing the presence of cypermethrin in California urban creeks at concentrations toxic to benthic invertebrates. Mitigation to address the ecological risks from agricultural and non-agricultural cypermethrin applications is described below.

a. Mitigation to Address Risks to Non-Target Organisms from Agricultural Uses

To address ecological risks from agricultural uses of cypermethrin, the following mitigation measures are required:

Decrease total yearly application rates, and increase re-treatment intervals

The maximum rate per application will be maintained at 0.1 lbs a.i./A for all crops. However, the following changes will be made to reduce the frequency of application and total pounds applied per year:

For cotton:

- Limit the total amount of product applied to 0.4 lbs ai/A/year (reduced from 0.6 lbs ai/A/year).
- Increase the minimum re-treatment interval to 5 days (increased from 3 days).

For pecans:

- Limit the total amount of product applied to 0.5 lbs ai/A/year (reduced from 0.6 lbs ai/A/year).
- Establish a minimum re-treatment interval of 7 days.

For head lettuce, head and stem brassicas (such as broccoli), leafy brassicas (such as canola), and bulb vegetables (such as onions):

- Limit the total amount of product applied to 0.6 lbs ai/A/year.
- Establish a minimum re-treatment interval of 7 days.

Prohibit high-rate, high-ecological-impact use sites

- Remove the use sites: agricultural uncultivated areas, fencerows, and hedgerows (application rate of 3.4 lbs ai/A) from product labels, and prohibit use on these sites
- Prohibit use on rights-of-way
- Prohibit use on sod farms

Require the following mitigation to reduce spray drift from agricultural applications

EPA understands the history of spray drift language development with the Pyrethroid Working Group (PWG), and the desire of registrants to maintain a level playing field among the pyrethroids with respect to spray drift restrictions. Since the current spray drift labeling for pyrethroids is over ten years old, EPA would like to update it as described below and in chapter 5 of this RED, and have all PWG pyrethroid products adopt these restrictions by early 2007. EPA is willing to meet with the PWG to discuss any issues concerning these spray drift label statements, and welcomes comments from other stakeholders during the 60-day post-RED comment period.

- For groundboom and aerial applications, use medium or coarser spray nozzles
- For motorized ground or aerial applications, apply only when the wind velocity is 3 to 10 mph for all crops other than cotton; for cotton, apply only when the wind velocity is 3 to 15 mph
- Do not make ground or aerial applications during temperature inversions
- For airblast applications to tree crops, direct spray into the canopy, and turn off outward pointing nozzles at row ends and when spraying outer two rows
- For groundboom, chemigation, or airblast applications, do not apply within 25 feet of water bodies or aquatic habitat
- For aerial applications, do not apply within 150 feet of water bodies or aquatic habitat; increase this no spray buffer zone to 450 feet when making an ultra low volume (ULV) application

- For aerial applications, do not release spray at a height greater than 10 feet above the ground or crop canopy, when spraying within 1000 feet of water bodies or aquatic habitat

See Section V and the label table for required spray drift label statements.

Require the following mitigation to reduce run-off from agricultural fields

- Construct and maintain a 10-foot-wide vegetative filter strip of grass or other permanent vegetation between the field edge and any water body or aquatic habitat (USDA, NRCS. 2000. Conservation Buffers to Reduce Pesticide Losses. Natural Resources Conservation Service. Fort Worth, Texas.)

c. Mitigation to Address Risks to Non-Target Organisms from Non-Agricultural Uses

Estimating risk from non-agricultural uses of pyrethroids

The Office of Pesticide Programs (OPP) strives to estimate pesticide exposure through all significant routes of exposure from both agricultural and non-crop uses. However, the ecological risk assessments for pyrethroid insecticides focus predominantly on the agricultural uses for these insecticides, because pesticide transport models are available to estimate potential aquatic exposure. Based on laboratory toxicity tests with terrestrial and aquatic animals, aquatic exposure would be more likely to cause adverse effects in the environment.

However, sales data indicate that non-crop uses of the pyrethroids comprise a much larger fraction of total use than agricultural uses. The use of pyrethroids in urban and suburban settings has increased since the phase-out of these uses of the organophosphate insecticides diazinon and chlorpyrifos. Sales data indicate that the majority of urban use of cypermethrin is for structural pest control, such as for control of termites or ants. Other outdoor non-crop uses include landscape maintenance, and homeowner lawn and garden use. Indoor uses include nuisance insect control, and termite applications.

For pyrethroids with relevant indoor uses (not including cypermethrin), the Agency uses a “down-the-drain” model to perform a screening-level aquatic risk assessment. In these simulations, waste water containing pesticide residue flows into a building drain and passes through a sanitary sewer and publicly owned treatment works (POTW) before being discharged to surface water. However, no analogous exposure model has been developed to allow a similar screening-level assessment for pesticides applied in an outdoor urban setting, like cypermethrin. As a result, the Agency has had to take a qualitative approach to characterize the potential aquatic risk from urban and suburban use of pyrethroids.

For outdoor urban uses, it is assumed that runoff water from rain and/or lawn watering may transport pesticides to storm sewers and then directly to surface water. Conceptually, a greater contribution to pyrethroid loading to surface water bodies would be expected from application to impervious surfaces such as walkways, driveways or the sides of buildings, than to lawns or bare ground, because of the pyrethroids’ strong affinity to bind to organic carbon in soils. However,

the Agency is unaware of any model which can simulate the different application methods for urban use and the physical representation of the urban landscape, storm sewer and receiving water configuration.

There are models available which can be calibrated to simulate sites and pesticides for which extensive flow and pollutant data have been collected in advance. The HSPF/NPSM model, for instance, which is included in the Office of Water's BASINS shell, has been used to calibrate stream flow and copper pesticide use data to simulate loading of these pesticides consistent with concentrations measured in surface water monitoring. Risk assessors with the California Department of Environmental Protection confirmed in conversations with the Agency that they also have used watershed models to calibrate to previously collected flow and pesticide monitoring data, but that they did not know of any models capable of predicting concentrations of pyrethroids that might occur because of outdoor urban uses.

Development of a screening model which could simulate the fate and transport of pesticides applied in an urban setting would require a large body of data which is currently unavailable. For instance, an urban landscape cannot be simulated as easily as an agricultural field. The PRZM model simulates runoff from an agricultural field using readily available data describing surface soil characteristics and laboratory data detailing the persistence and mobility of pesticides in these soils. The agricultural field simulated is homogeneously planted to a single crop, and soil and water are transported from the field to a receiving water body with dimensions consistent with USDA farm-pond construction guidelines.

By contrast, an urban landscape or suburban housing development consists of impervious surfaces such as streets and sidewalks, and pervious surfaces such as lawns and parkland. One could expect much greater mobility for pesticides applied to impervious surfaces, but laboratory soil metabolism studies may not provide an accurate measure of the persistence of pesticides on these surfaces. The path runoff water and eroded sediment might take is less obvious for an urban setting than an agricultural field. First, an urban landscape cannot be considered homogeneous, as the proportion of impervious and pervious surfaces varies for different locations. In addition, the flow path of runoff water and sediment is not necessarily a direct path over land, but can pass below ground through storm sewer networks, or be directed or slowed by pumping stations or temporary holding ponds.

Finally, the timing and magnitude of urban uses is less well defined for urban uses than agricultural uses. While agricultural uses would occur within a predictable window during the growing season, the need for urban uses could occur at different times each year, and might occur at different times within the same watershed. In addition, since records of how and to what extent pyrethroids are applied by homeowners are less well defined than for professional applications, it is harder to estimate the total load to model.

Pyrethroid monitoring data

The Agency considers surface water monitoring data in addition to modeling results when they are available. However, surface water monitoring for pyrethroids has been limited, perhaps because the pyrethroids would more likely be associated with aquatic sediment than the water

column. The USGS NAWQA program included permethrin (another pyrethroid currently undergoing reregistration) as the only pyrethroid among its pesticide analytes, and detected it in 0.15% of 1185 agricultural stream samples from 78 sample locations. Permethrin was not detected in 803 urban stream samples taken from 33 sample locations. The NAWQA program also analyzed for *cis*-permethrin in bed sediments, and had similar detection rates in between the agricultural (1.5%) and urban (1.0%) land use sites; *trans*-permethrin was detected in 0.8% of bed sediment samples.

More recently, researchers from the University of California-Berkeley have published studies which reported transport of pyrethroids to stream bed sediment as a result of urban uses. In 2004, Weston, et al. collected sediment from creeks draining a residential area in Rosedale, California. The sediments were analyzed for 7 pyrethroids (including cypermethrin and permethrin), as well as for other insecticides. All of the pyrethroids were detected in the bed sediment from at least one sampling location. The researchers exposed the aquatic amphipod *Hyaella azteca* to the 21 sediment samples they collected; pesticide concentrations in 9 of these samples was sufficient to cause 90% mortality in the amphipods after a 10-day exposure. The concentrations of pyrethroids detected in the sediments were above the level expected to cause 50% mortality in *H. azteca*, suggesting that the pyrethroids were responsible for the observed toxicity.

In a subsequent study, Weston, et al. collected samples from 15 urban creeks in California and 12 in Tennessee. Toxicity to *H. azteca* was observed at least once with sediments taken from 12 of the 15 California sampling sites. In most cases, the toxicity could be accounted for by the concentrations of pyrethroids detected in the sediment. Pyrethroids were rarely detected in the Tennessee sediment samples, and exposure to the Tennessee sediments did not prove to be toxic to *H. azteca*.

Future steps

The results of the Weston, et al. studies has led a number of organizations, such as the California State Water Resources Control Board (SWRCB) to submit comments to the Agency during the reregistration process of several pyrethroid insecticides, calling for mitigation measures to prevent pyrethroid surface-water contamination. However, the lack of knowledge which makes it difficult to develop an urban pesticide transport model also makes it difficult to identify meaningful mitigation at this time. The Agency has developed some initial mitigation options during the reregistration process, and intends to identify steps which can be taken to allow a greater understanding of potential ecological risk from urban pyrethroid uses.

One reason that broad mitigation measures cannot be adopted during reregistration is that only three pyrethroid insecticides are required to be reviewed for reregistration in accordance with FQPA. If use restrictions were placed on one of these three pesticides, one of the other pyrethroids would likely replace it for that use. It is important, as some commenters have suggested, to perform a risk assessment for all of the pyrethroids at the same time. The Weston papers indicated that the sediments which proved toxic to the tested aquatic invertebrate were contaminated not only with the pyrethroids undergoing reregistration, but also other pyrethroids such as bifenthrin and lambda-cyhalothrin.

The next opportunity to assess the pyrethroids as a group will occur during the Registration Review program, for which the Agency issued a proposed rule in July 2005 and plans to issue the final rule and implement the program in 2006. The purpose of Registration Review is to ensure the periodic review of all pesticides to make sure they continue to meet current scientific and regulatory requirements, with the goal of reviewing each pesticide every fifteen years. The pyrethroids are tentatively scheduled for re-evaluation under the proposed Registration Review program in 2010.

A number of steps are planned for the intervening years which should improve the Agency's ability to assess the level of aquatic exposure to pyrethroids from urban use. One step is to better identify what conditions in an urban setting might lead to greater vulnerability to transport to urban water bodies. Although the Weston papers reported sediment toxicity from samples from California but not Tennessee, the authors could only speculate what differences in use or geography made an area more vulnerable to exposure than the other.

Further investigation into the dominant urban uses and application practices of pyrethroids around the country would help provide a clearer picture of relative vulnerability. The SWRCB commented that structural pest control is likely a major source of pyrethroids in urban runoff, and suggested best management practices (BMP). The Pyrethroid Working Group (PWG) indicated that irrigation of lawns in areas of California with little rainfall during the application season could be a major contributor, and has contacted organizations such as Responsible Industry for a Sound Environment (RISE) and the Coalition for Urban/Residential Environmental Stewardship (CURES) to develop BMPs as part of their product stewardship plan. As further sediment monitoring studies are published describing parts of the country with different weather and pest pressures, more detailed usage data will make it easier to correlate the causes of pyrethroid use practices.

The Agency will also continue in its efforts to develop a screening-level model for urban pesticide uses. Advances in the resolution of GIS databases may allow better representation of the impervious and pervious portions of a typical urban landscape. As it becomes clearer which uses are most likely to lead to transport of pyrethroids to surface water, the conceptual model of how urban transport should be simulated will be more focused.

Finally, the Agency will evaluate available published literature and call-in data to resolve data gaps to ensure a robust comparison of the potential ecological risk of all the pyrethroids during Registration Review. Toxicity data cited by several commenters from published literature are included in the Agency's ECOTOX database. The Agency will evaluate the quality of studies to identify those to be included in the risk assessments during Registration Review. The PWG has performed some toxicity studies identified by the Agency as data gaps, such as sediment invertebrate toxicity tests and those studies are in review.

Interim mitigation required for reregistration

Until the Agency can perform a quantitative risk assessment for the non-agricultural uses of cypermethrin, the Agency believes that certain interim mitigation measures are warranted. These mitigation measures are intended to reduce the runoff and drainage to storm sewers, surface

water, and aquatic habitats associated with the current industrial, commercial, and residential uses of cypermethrin, and to address potential risks to aquatic organisms from these existing use patterns. These mitigation measures should also help to reduce off-site exposure and risk to terrestrial organisms.

To reduce runoff and drift to water bodies, and to address potential ecological risks from non-agricultural (industrial, commercial, and residential) uses of cypermethrin, the following mitigation measures are required:

For products with indoor and/or outdoor nuisance pest control uses (other than termiticides)

- Limit all outdoor non-termite applications to spot and crack-and-crevice applications, only, except for the following barrier, perimeter, band or broadcast spray applications, which are permitted:
 - (1) Barrier, perimeter or band applications to soil or vegetation around structures;
 - (2) Broadcast applications to vegetated residential or commercial landscapes, including lawns and turf;
 - (3) Band applications to building foundations, up to a maximum height of 3 feet.Other than number (3), above, all outdoor non-termite applications to impervious surfaces such as sidewalks, driveways, patios, porches and structural surfaces (such as windows, doors, and eaves) are limited to spot and crack-and-crevice applications, only.
- Reduce the maximum broadcast application rate for residential, commercial, and industrial lawns to 0.44 lbs ai/A (0.0101 lbs ai/1000 ft²) for all formulations. (Maximum rate was 0.74 lbs ai/A).
- For outdoor uses, do not apply within 10 feet of storm drains. Do not apply within 25 feet of rivers, fish ponds, lakes, streams, reservoirs, marshes, estuaries, bays, or oceans.
- Prohibit application directly into drains, or to any area where drainage to storm sewers, water bodies, or aquatic habitat can occur. When making an application around or near a floor drain, limit the application to a spot treatment and do not allow the product to enter the drain during or after the application. The use site “Application around or near floor drains” should be listed separately from other indoor use sites on the label, with these restrictions.
- Broadcast applications to exterior surfaces of boats are prohibited. Applications to exterior surfaces of boats are limited to spot treatments, only. Use inside boats, ships, and other vessels is permitted. Do not allow product to drain or wash off into water bodies or aquatic habitat. The use site “Application in and on boats” should be listed separately from other use sites on the label, with these restrictions.
- Cover any water inhabited by fish (such as aquariums and ornamental fish ponds) during treatment, and turn aquarium systems off.
- Remove birds and other pets. Do not allow pets to enter treated areas or contact treated surfaces until sprays have dried.
- Do not apply when windy (sustained wind speeds or gusts above 10 mph).
- After application, do not over-water the treated area to the point of runoff. Do not apply when raining or when rain is expected within 8 hours.

- Rinse application equipment over lawn or garden area only. Do not allow rinse water to flow into drains (including storm drains), street gutters, sewers, drainage ditches, water bodies, or aquatic habitat.

Comments were received concerning use of cypermethrin in “swimming pool water systems.” Application to swimming pool water systems, or to swimming pools in general, is not a labeled use of cypermethrin. Cypermethrin may be applied as a broadcast treatment to lawns and other vegetated areas around swimming pools, or as a spot or crack-and-crevice treatment to impermeable surfaces (such as tiled walkways) around pools.

A granular product was registered on February 23, 2006 (EPA registration # 28293-367). This product is for application to fire ant mounds on lawns and outside of homes. EPA does not believe that this product, when used according to label directions (very limited, targeted use), presents a risk of concern to non-target organisms.

For pre-construction subterranean termite control

During the phase 3 comment period for cypermethrin, EPA received comments from California water regulatory agencies concerning the potential for runoff and aquatic risk from pre-construction (non-injected) termite applications. Commenters also submitted label statements for this use. After receiving input from the Association of Structural Pest Control Regulatory Officials (ASPCRO), EPA developed the proposed label statements listed below. EPA would like to invite further stakeholder input on these statements during the post-RED comment period for cypermethrin.

- (1) If concrete slabs cannot be poured over the treated soil on the day of application, the treated soil must be covered with a waterproof covering (such as polyethylene sheeting).
- (2) Do not treat soil that is water-saturated or frozen. Do not treat when raining or when rain is expected within 8 hours. All treated areas must be covered (with a waterproof covering) before it starts to rain. If a waterproof cover is used, storm water runoff must be diverted around the treatment area to prevent water from contacting or collecting in the treatment area.
- (3) Do not apply within 10 feet of storm drains. Do not apply within 25 feet of rivers, fish ponds, lakes, streams, reservoirs, marshes, estuaries, bays, or oceans.
- (4) Do not make on-grade applications when sustained wind speeds or gusts are above 10 mph.

c. Endangered Species

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may

affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at that time.

Following this future species-specific analysis, a determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in: limitations on the use of cypermethrin, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service or the National Marine Fisheries Service as necessary. If the Agency determines use of cypermethrin “may affect” listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to cypermethrin at levels of concern. EPA is not requiring specific cypermethrin label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

3. Benefits of Cypermethrin Use and Available Alternatives

Pyrethrin and synthetic pyrethroids, including cypermethrin, cyfluthrin, deltamethrin, esfenvalerate, lambda cyhalothrin, permethrin, resmethrin, sumithrin, tetramethrin, and tralomethrin, are available to control a wide variety of nuisance, lawn and garden plant, structural, and public health arthropod pests. Pyrethroids may be applied inside residential areas as a crack and crevice, area, or spot spray. They may also be applied in areas adjacent to or surrounding residential areas as a perimeter treatment to prevent the movement of pests into houses and as a spot and yard treatment. Usage data are sparse and generally do not distinguish between chemicals within the class or differentiate the amounts used on various residential sites. The recent loss of chlorpyrifos and diazinon for residential pest control has resulted in a greater reliance on pyrethrins and synthetic pyrethroids, as a class, among residential users. Most pyrethroids have similar efficacy and cost. In the absence of any one pyrethroid, homeowners and professional applicators would most likely simply substitute another pyrethroid insecticide. Users might also substitute insecticides from other chemical classes (e.g. organophosphates, carbamates, and neonicotinoids) and nonchemical control techniques (e.g. sanitation or exclusion). Given the options for substitution, the economic impacts of restricting any one chemical would not likely be significant; also, the impact on risk of restricting any one pyrethroid is uncertain and might increase given the substitute available.

V. What Registrants Need to Do

The Agency has determined that cypermethrin is eligible for reregistration provided that the mitigation measures and label changes identified in this RED are implemented. Registrants will need to amend their product labeling to incorporate the label statements set forth in the Label

Changes Summary Table (table 16). The Agency intends to issue Data Call-Ins (DCIs) requiring generic and product specific data. Generally, the registrant will have 90 days from receipt of a DCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of cypermethrin for currently registered uses has been reviewed and determined to be substantially complete. However, the data listed below are necessary to confirm the reregistration eligibility decision documented in this RED.

Table 15. Guideline Requirements for Cypermethrin		
Data Requirement	Old Guideline Number	New OPPTS Guideline No.
Life-Cycle Aquatic Invertebrate, Freshwater:	72-4 (b)	850.1350

Additional Residue Chemistry Clarifications

Other needed label changes pertain to the following: 1) minimum retreatment intervals, 2) minimum aerial application volumes, and 3) impractical cotton forage grazing/feeding restrictions.

2. Labeling Requirements

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 16.

3. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, the EPA will continue to work with all interested parties on this important issue.

B. End-Use Products

Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if

not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements. For any questions regarding the PDCI, please contact Jane Mitchell at (703) 308-8061.

Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in table 16. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

Labeling Changes Summary Table 16

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 16. Summary of Labeling Changes for Cypermethrin		
Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	<p>“Only for formulation into an <i>insecticide</i> for the following use(s) [fill blank only with those uses that are being supported by MP registrant].”</p> <p>“This product may not be formulated into wettable powder end use formulations unless they are packaged in water soluble bags.”</p>	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	<p>“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p>	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies [LOOK UP IN LABEL REVIEW MANUAL]	<p>“This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.”</p>	Precautionary Statements
End Use Products for WPS (agricultural) use ONLY		

<i>(products labeled for non-agricultural occupational uses must have separate registrations: see below for requirements)</i>		
Restricted Use Pesticide required for all products.	<p>“RESTRICTED USE PESTICIDE Due to Toxicity to Fish and Aquatic Organisms. For retail sale to and use only by certified applicators or persons under the direct supervision and only for those uses covered by the certified applicator’s certification.”</p>	
<p>PPE Requirements Established by the RED¹</p> <p>For Wettable Powder (only wettable powder formulations packaged in water soluble bags will be eligible for reregistration).</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G, or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> > Long-sleeve shirt and long pants, > Shoes plus socks, > Chemical resistant gloves for applicators using handheld equipment.” <p>“Human flagging is prohibited.”</p> <p>See engineering controls for additional requirements.</p>	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
<p>PPE Requirements Established by the RED¹</p> <p>For Emulsifiable Concentrate</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G, or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> > Long-sleeve shirt and long pants, > Shoes plus socks, > Chemical resistant gloves for applicators using handheld equipment.” <p>“Human flagging is prohibited.”</p>	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

User Safety Requirements	<p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.</p> <p>Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”</p>	Immediately following the PPE requirements
Engineering controls for Wettable Powder Formulations	<p>“Engineering controls</p> <p>Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must :</p> <ul style="list-style-type: none"> -- wear the personal protective equipment required in the PPE section of this labeling for mixers and loaders, and -- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown a NIOSH-approved respirator with: -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C <i>or</i> -- any N, R, P, or HE filter.” <p><i>Instruction to Registrant:</i> Drop the “N” type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil.</p> <p>“Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].”</p> <p>“Human flagging is prohibited. Flagging to support aerial application is limited to use of the Global Positioning System (GPS) or mechanical flaggers.”</p>	Immediately following the User Safety Requirements
Engineering controls for Liquids	<p>“Pilots must use an enclosed cockpit that meet the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].</p>	Immediately following the User Safety Requirements

	<p>“Human flagging is prohibited. Flagging to support aerial application is limited to use of the Global Positioning System (GPS) or mechanical flaggers.”</p>	
User Safety Recommendations	<p>“User Safety Recommendations</p> <p>Users should wash hands with plenty of soap and water before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	<p>Immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p>
Environmental Hazards	<p>“This product is extremely toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters.”</p> <p>“This pesticide is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops if bees are visiting the treatment area.”</p>	<p>Precautionary Statements immediately following the User Safety Recommendations</p>
Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS)	<p>“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.”</p>	<p>Directions for Use, In Agricultural Use Requirements Box</p>
Early Entry Personal Protective Equipment	<p>For minimum early entry PPE use the following:</p> <p>“PPE required for early entry to treated areas that is permitted under the</p>	<p>Direction for Use, In Agricultural Use Requirements box, immediately following the</p>

for products with directions for use within the scope of the WPS	<p>Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:</p> <ul style="list-style-type: none"> * coveralls, * shoes plus socks * chemical-resistant gloves made of any waterproof material” 	REI
General Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”	Place in the Direction for Use directly above the Agricultural Use Box.
Other Application Restrictions (Risk Mitigation)	<p>“Construct and maintain a 10-foot-wide vegetative filter strip of grass or other permanent vegetation between the field edge and any water body or aquatic habitat (such as lakes, reservoirs, rivers, streams, marshes, natural ponds, estuaries, and commercial fish ponds). Refer to the following publication for information on constructing and maintaining effective vegetative buffers: USDA, NRCS. 2000. Conservation buffers to Reduce Pesticide Losses. Natural Resources Conservation Service. Fort Worth, Texas. 21 pp.”</p> <p>“Use on sod farms, agricultural uncultivated areas, fencerows, hedgerows, and rights-of-way is prohibited.” These use sites must be removed from all product labels. Special Local Need registrations with these uses must be cancelled.</p> <p>Products must be amended to reflect the following maximum application rates (ai/A), minimum retreatment intervals and maximum annual application rates</p> <p><u>Cotton:</u></p> <p>Maximum application rate of 0.1 lb ai/A</p> <p>Minimum retreatment interval of 5 days</p> <p>Maximum seasonal application rate of 0.4 lbs ai/A</p> <p>“Do not make more than 10 synthetic pyrethroid applications (of one product or combinations of products) to cotton in one growing season.”</p>	Directions for Use

	<p><u>Pecans:</u> Maximum application rate of 0.1 lb ai/A Minimum retreatment interval of 7 days Maximum seasonal application rate of 0.5 lbs ai/A</p> <p><u>Head lettuce:</u> Maximum application rate of 0.1 lb ai/A Minimum retreatment interval of 7 days Maximum seasonal application rate of 0.6 lbs ai/A</p> <p><u>All other crops:</u> Maximum application rate of 0.1 lb ai/A Minimum retreatment interval of 7 days Maximum seasonal application rate of 0.4 lbs ai/A</p>	
Spray Drift	<p><u>"Spray drift requirements</u></p> <p>(1) For groundboom and aerial applications, use only Medium or coarser spray nozzles according to ASABE (S572) definition for standard nozzles. Aerial applicators must consider flight speed and nozzle orientation in determining droplet size.</p> <p>(2) For cotton: make aerial or ground applications when the wind velocity is 3 to 15 mph. Do not apply when the wind speed is greater than 15 mph. For all non-aerial applications, wind speed must be measured adjacent to the application site on the upwind side, immediately prior to application.</p> <p>(3) For all crops other than cotton: make aerial or ground applications when the wind velocity is 3 to 10 mph. Do not apply when the wind speed is greater than 10 mph. For all non-aerial applications, wind speed must be measured adjacent to the application site on the upwind side, immediately prior to application.</p>	Directions for Use

	<p>(4) Do not make aerial or ground applications into temperature inversions.</p> <p>(5) For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy.</p> <p>(6) For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. To minimize spray loss over the top in orchard applications, spray must be directed into the canopy.</p> <p>(7) For ground-boom, chemigation, or airblast applications, do not apply within 25 feet of water bodies or aquatic habitat (such as lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds).</p> <p>(8) For aerial application, do not apply within 150 feet of water bodies or aquatic habitat (such as lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds). Increase the no spray buffer zone to 450 feet when making an ultra low volume (ULV) application.</p> <p>(9) For aerial applications, do not release spray at a height greater than 10 feet above the ground or crop canopy when spraying within 1000 feet of water bodies or aquatic habitat.</p> <p>(10) For aerial applications, the outermost nozzles must not exceed 60% of the wingspan or 80% of the rotor blade diameter.</p> <p>(11) When aerial applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind.”</p>	
End Use Products Primarily Intended for Occupational Use (Non-Agricultural)		

<p>PPE Requirements Established by the RED¹</p> <p>For Wettable Powder Products (only wettable powder formulations packaged in water soluble bags will be eligible for reregistration).</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> > Long-sleeve shirt and long pants, > Shoes plus socks, > Chemical resistant gloves.” 	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>PPE Requirements Established by the RED¹</p> <p>For Emulsifiable Concentrate, Dry Flowable and Granular Products</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> > Long-sleeve shirt and long pants, > Shoes plus socks, > Chemical resistant gloves.” 	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>PPE Requirements Established by the RED¹</p> <p>For Ready-To-Use Products (total release foggers, aerosols, pump sprays, wipes, ear tags)</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> > Long-sleeve shirt and long pants, > Shoes plus socks.” 	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>User Safety</p>	<p>“Follow manufacturer’s instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep</p>	<p>Immediately following the PPE requirements</p>

Requirements	<p>and wash PPE separately from other laundry.</p> <p>Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."</p>	
Environmental Hazard Statements	<p>For products that have outdoor uses:</p> <p>"This product is extremely toxic to fish. Do not apply directly to or near water. Drift and run-off may be hazardous to fish in water adjacent to treated areas. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements."</p> <p><i>[CHECK THIS - - ADD: "AND OTHER AQUATIC ORGANISMS" ?]</i></p>	
Entry Restrictions for Products Applied as a Spray	"Do not allow children or pets to contact treated surfaces until sprays have dried."	Directions for Use Under General Precautions and Restrictions.
Entry Restrictions for Total Release Fogger Products	<i>[INSERT VENTILATION REQUIREMENTS HERE?]</i>	
Hazards to Humans and Domestic Animals	<p><i>[THERE ARE A NUMBER OF STATEMENTS ALREADY ON LABELS (SEE P.2 OF 11715-355, FOR EXAMPLE.)]</i></p> <p>"Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling."</p>	
General Application Restrictions	"Do not apply this product in a way that will contact people or pets, either directly or through drift."	Directions for Use Under General Precautions and Restrictions.
Application Restrictions	<p><u>For nuisance pest control products (other than termiticides)</u></p> <p>Products (all formulations) must be amended to reflect the following maximum application rate (ai/A):</p>	Directions for Use Under General Precautions and Restrictions.

	<p><u>Residential, commercial, and industrial lawns</u>: Maximum application rate of 0.44 lbs ai/A (0.0101 lbs ai/1000 ft²).</p> <p>“Limit all outdoor applications to spot and crack-and-crevice applications, only, <u>except</u> for the following barrier, perimeter, band or broadcast spray applications, which are permitted:</p> <ul style="list-style-type: none"> • Barrier, perimeter or band applications to soil or vegetation around structures; • Broadcast applications to vegetated residential or commercial landscapes, including lawns and turf; • Band applications to building foundations, up to a maximum height of 3 feet. <p>Other than number (3), above, all outdoor applications to <u>impervious surfaces</u> such as sidewalks, driveways, patios, porches and structural surfaces (such as windows, doors, and eaves) are limited to <u>spot and crack-and-crevice applications</u>, only.”</p> <p>Application to swimming pool water systems, or to swimming pools in general, is not a labeled use of cypermethrin. Cypermethrin may be applied as a broadcast treatment to lawns and other vegetated areas <u>around</u> swimming pools, or as a spot or crack-and-crevice treatment to impermeable surfaces (such as tiled walkways) <u>around</u> pools.</p> <p>“<u>Do not apply directly into drains</u>, or to any area where drainage to storm sewers, water bodies, or aquatic habitat can occur. When making an application around or near a floor drain, limit the application to a spot treatment and <u>do not allow the product to enter the drain</u> during or after the application.” The use site “Application around or near floor drains” must be listed separately from other indoor use sites on the label, with these restrictions.</p> <p>“For outdoor uses, do not apply within 10 feet of storm drains. Do not apply within 25 feet of rivers, fish ponds, lakes, streams, reservoirs, marshes, estuaries, bays, and oceans.”</p> <p>“Broadcast applications to exterior surfaces of boats are prohibited.</p>	
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	<p>Applications to exterior surfaces of boats are limited to spot treatments, only. Use inside boats, ships, and other vessels is permitted. Do not allow product to drain or wash off into water bodies or aquatic habitat.” The use site “Application in and on boats” must be listed separately from other use sites on the label, with these restrictions.</p> <p>“Do not apply when windy (sustained wind speeds or gusts above 10 mph).”</p> <p>“After application, do not over-water the treated area to the point of runoff. Do not apply when raining or when rain is expected within 8 hours of application.”</p> <p>“Rinse application equipment over lawn or garden area only. Do not allow rinse water to flow into drains (including storm drains), street gutters, sewers, drainage ditches, water bodies, or aquatic habitat.”</p> <p>“Do not allow applications to contact water inhabited by fish, such as aquariums and ornamental fish ponds that are located in/near structures being treated. Cover any water inhabited by fish during treatment, and turn aquarium systems off.”</p> <p><i>STATEMENTS CURRENTLY ON SOME PRODUCT LABELS (SHOULD BE MAINTAINED AND ADDED TO ALL APPROPRIATE PRODUCTS):</i></p> <p>“Do not use water-based sprays in conduits, motor housings, junction boxes, switch boxes, or other electrical equipment because of possible shock hazard.”</p> <p>“Do not apply to pets.” <i>[NOTE: DO WE NEED AN ADDITIONAL WARNING ABOUT HIGH TOXICITY TO CATS?]</i></p> <p>“Do not use as a space spray.”</p> <p>“Use only in well-ventilated areas.”</p>	
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	<p>“During any indoor surface application, do not allow dripping or runoff to occur. During any application to ceilings of a structure, cover surface below with plastic shielding or similar material.”</p> <p>“Do not apply this product in any room being used as a living, eating, or recovery area by patients, the elderly, or infirm when they are in the room.”</p> <p>“Do not apply to classrooms when in use.”</p> <p>“Do not apply to areas of institutions (including libraries, sport facilities, etc.) when occupants are present in the immediate treatment area.”</p> <p>“Not labeled for use in food areas. Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared foods are served, such as dining rooms, but excluding areas where foods may be prepared or held. In the home, all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed food should be covered or removed.”</p> <p>“Do not use in warehouses where raw or cured tobacco is stored.”</p> <p>“Do not use in warehouses while raw agricultural commodities for food or feed are being stored.”</p> <p>“Do not use in greenhouses where crops for food or feed are grown.”</p> <p>“Do not apply to aircraft cabins.”</p> <p>“Do not use concentrate or emulsion in fogging equipment.”</p> <p><u>For subterranean termite control</u></p>	
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	<p>Maintain, modify, or add the following statements to product labels: <i>[SHOULD WE ADD ANY OTHER STATEMENTS FROM THE SYNGENTA LABEL, BELOW?]:</i></p> <p>“Use anti-backflow equipment or procedures to prevent siphonage of pesticide back into water supplies.”</p> <p>“Do not treat soil beneath structures that contain wells or cisterns.”</p> <p>“Care should be taken that the treatment solution is not introduced into the gravel and/or pipe drainage system which may be located on the exterior of the foundation in close proximity to the footing of the structure.”</p> <p>“Care must be taken to avoid runoff. Do not treat soil that is water-saturated or frozen. Do not treat when raining or when rain is expected within 8 hours.”</p> <p>“Consult state and local specifications for recommended distance of treatment areas from wells. Refer to Federal Housing Administration Specifications for guidance on preconstruction treatments.”</p> <p><u>For pre-construction subterranean termite control</u></p> <p>“If concrete slabs cannot be poured over the treated soil on the day of application, the treated soil must be covered with a waterproof covering (such as polyethylene sheeting).”</p> <p>“Do not treat soil that is water-saturated or frozen. Do not treat when raining or when rain is expected within 8 hours. All treated areas must be covered (with a waterproof covering) before it starts to rain. Storm water runoff must be diverted around the treatment area to prevent water from contacting or collecting in the treatment area.”</p> <p>“Do not apply within 10 feet of storm drains. Do not apply within 25 feet of rivers, fish ponds, lakes, streams, reservoirs, marshes, estuaries, bays,</p>	
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	<p>or oceans.”</p> <p>“Do not make on-grade applications when sustained wind speeds or gusts are above 10 mph.”</p> <p>“Whenever possible, make termite control applications near the structure foundation using soil injection.”</p> <p><u>For all termiticide products</u></p> <p>“All leaks resulting in the deposition of termiticide in locations other than those prescribed on this label must be cleaned up prior to leaving the application site. Do not allow people or pets to contact contaminated areas or to reoccupy the contaminated area of the structure until the clean up is completed.” [THIS STATEMENT IS ON A CURRENT SYNGENTA PRODUCT]</p> <p>[Other statements on current Syngenta termiticide label:</p> <p>“Structures with adjacent well/cisterns and/or other water bodies.”</p> <p>“Applicators must inspect all structures with nearby water sources such as wells, cisterns, surface ponds, streams, and other bodies of water and evaluate, at a minimum, the treatment recommendations listed below prior to making an application.</p> <ol style="list-style-type: none"> 1. Prior to treatment, if feasible, expose the water pipe(s) coming from the well to the structure, if the pipe(s) enter the structure within 3 ft. of the grade. 2. Prior to treatment, applicators are advised to take precautions to limit the risk of applying the termiticide into subsurface drains that could empty into any bodies of water. These precautions include evaluating whether application of the termiticide to the top of the footer may result in contamination of the subsurface drain. Factors such as depth to the drain system and soil type and degree of compaction should be taken into account in determining the depth of treatment. 	
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	3. When appropriate (i.e., on the water side of the structure), the treated backfill technique (described above) can also be used to minimize off-site movement of the termiticide.”]	
End Use Products Primarily Intended for Residential Use		
Environmental Hazard Statements	<p>For products that have outdoor uses:</p> <p>“This product is extremely toxic to fish. Do not apply directly to or near water. Drift and run-off may be hazardous to fish in water adjacent to treated areas. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements.”</p> <p><i>[CHECK THIS - - ADD: “AND OTHER AQUATIC ORGANISMS” ?]</i></p>	
Entry Restrictions for products applied as a spray	“Do not allow children or pets to contact treated surfaces until sprays have dried.”	Directions for use under General Precautions and Restrictions
Entry Restrictions for Total Release Fogger Products	<i>[INSERT VENTILATION REQUIREMENTS HERE?]</i>	
Hazards to Humans and Domestic Animals	<p><i>[THERE ARE A NUMBER OF STATEMENTS ALREADY ON LABELS (SEE P.2 OF 11715-355, FOR EXAMPLE.)]</i></p> <p>“Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.”</p>	
General Application Restrictions	“Do not apply this product in a way that will contact any person, pet, either directly or through drift. Keep people and pets out of the area during application.”	Directions for Use under General Precautions and Restrictions

<p>Additional Application Restrictions</p>	<p><i>[ARE ANY OF THESE STATEMENTS NOT APPROPRIATE FOR A HOMEOWNER LABEL?]</i></p> <p>Products (all formulations) must be amended to reflect the following maximum application rate (ai/A):</p> <p><u>Residential lawns:</u> Maximum application rate of 0.44 lbs ai/A (0.0101 lbs ai/1000 ft²).</p> <p>“Limit all outdoor applications to spot and crack-and-crevice applications, only, <u>except</u> for the following barrier, perimeter, band or broadcast spray applications, which are permitted:</p> <ul style="list-style-type: none"> • Barrier, perimeter or band applications to soil or vegetation around structures; • Broadcast applications to vegetated residential or commercial landscapes, including lawns and turf; • Band applications to building foundations, up to a maximum height of 3 feet. <p>Other than number (3), above, all outdoor applications to <u>impervious surfaces</u> such as sidewalks, driveways, patios, porches and structural surfaces (such as windows, doors, and eaves) are limited to <u>spot and crack-and-crevice applications</u>, only.”</p> <p>Application to swimming pool water systems, or to swimming pools in general, is not a labeled use of cypermethrin and must be removed from product labels. Cypermethrin may be applied as a broadcast treatment to lawns and other vegetated areas <u>around</u> swimming pools, or as a spot or crack-and-crevice treatment to impermeable surfaces (such as tiled walkways) <u>around</u> pools.</p> <p>“<u>Do not apply directly into drains</u>, or to any area where drainage to storm sewers, water bodies, or aquatic habitat can occur. When making an application around or near a floor drain, limit the application to a spot treatment and <u>do not allow the product to enter the drain</u> during or after the application.” The use site “Application around or near floor drains”</p>	<p>Directions for Use under General Precautions and Restrictions</p>
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	<p>must be listed separately from other indoor use sites on the label, with these restrictions.</p> <p>“For outdoor uses, do not apply within 10 feet of storm drains. Do not apply within 25 feet of rivers, fish ponds, lakes, streams, reservoirs, marshes, estuaries, bays, and oceans.”</p> <p>“Broadcast applications to exterior surfaces of boats are prohibited. Applications to exterior surfaces of boats are limited to spot treatments, only. Use inside boats, ships, and other vessels is permitted. Do not allow product to drain or wash off into water bodies or aquatic habitat.” The use site “Application in and on boats” must be listed separately from other use sites on the label, with these restrictions.</p> <p>“Do not apply when windy (sustained wind speeds or gusts above 10 mph).”</p> <p>“After application, do not over-water the treated area to the point of runoff. Do not apply when raining or when rain is expected within 8 hours of application.”</p> <p>“Rinse application equipment over lawn or garden area only. Do not allow rinse water to flow into drains (including storm drains), street gutters, sewers, drainage ditches, water bodies, or aquatic habitat.”</p> <p>“Do not allow applications to contact water inhabited by fish, such as aquariums and ornamental fish ponds that are located in/near structures being treated. Cover any water inhabited by fish during treatment, and turn aquarium systems off.”</p> <p><i>STATEMENTS CURRENTLY ON SOME PRODUCT LABELS (SHOULD BE MAINTAINED AND ADDED TO ALL APPROPRIATE PRODUCTS):</i></p> <p>“Do not use water-based sprays in conduits, motor housings, junction boxes, switch boxes, or other electrical equipment because of possible shock hazard.”</p>	
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	<p>“Do not apply to pets.” <i>[NOTE: DO WE NEED AN ADDITIONAL WARNING ABOUT HIGH TOXICITY TO CATS?]</i></p> <p>“Do not use as a space spray.”</p> <p>“Use only in well-ventilated areas.”</p> <p>“During any indoor surface application, do not allow dripping or runoff to occur. During any application to ceilings of a structure, cover surface below with plastic shielding or similar material.”</p> <p>“Do not apply this product in any room being used as a living, eating, or recovery area by patients, the elderly, or infirm when they are in the room.”</p> <p>“Do not apply to classrooms when in use.”</p> <p>“Do not apply to areas of institutions (including libraries, sport facilities, etc.) when occupants are present in the immediate treatment area.”</p> <p>“Not labeled for use in food areas. Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared foods are served, such as dining rooms, but excluding areas where foods may be prepared or held. In the home, all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed food should be covered or removed.”</p> <p>“Do not use in greenhouses where crops for food or feed are grown.”</p> <p>“Do not use concentrate or emulsion in fogging equipment.”</p>	

¹ PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

² If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” designation must be dropped.

Appendix A. Uses of Cypermethrin Eligible for Reregistration

Crop	Typical Application Rate (lbs ai/acre)	Maximum/Rescue Application Rate(lbs ai/acre)	Maximum Total Pounds A.I. Applied Per Acre Per Year	Maximum Number of Applications	Minimum Retreatment Interval	Application Method	REI	Pre Harvest Interval (PHI)

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

To be added.

Appendix C. Technical Support Documents

To be added

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Eligibility Decision

MRID	Citation
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00034562	
00035127	
00058170	
00089415	

Accession Number	Citation
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130888	Howard, D.J. and C.D. Johnston. 1971. CYTOX 2160 - Safety Evaluation by Single Oral Administration to Bobwhite Quail. Unpublished Study Conducted by Woodard Research Corporation for American Cyanamid Co.
131455	Johnston, C.D. 1971. CYTOX 2160 - Safety Evaluation by Single Oral Administration to Mallard Ducks. Unpublished Study Conducted by Woodard Research Corporation for American Cyanamid Co.
132149	Sleight, Bevier Hasbrouck. 1971. The Acute Toxicity of CYTOX 2160 (ST 45093) to Bluegill (<i>Lepomis macrochirus</i>) and Rainbow Trout (<i>Oncirynchus mykiss</i> formerly <i>Salmo gairdneri</i>). Unpublished Study Conducted by Bionomics, Inc. for American Cyanamid Co.
226855	Fink, R. 1976. Eight-Day Dietary LC50 - Bobwhite quail - CYTOX 2160. Unpublished Study Conducted by Wildlife International for Union Carbide Corp. Submitted by American Cyanamid Company.